GLYCEMIC CONTROL IN CHILDREN WITH TYPE 1 DIABETES MELLITUS- PREDICTORS AND IMPLICATIONS

Dissertation submitted to

THE TAMILNADU

DR .M.G.R.MEDICAL UNIVERSITY,CHENNAI

With Partial fulfillment of the regulations

For the award of the Degree of

MD PAEDIATRICS

(BRANCH VII)

INSTITUTE OF CHILD HEALTH AND

HOSPITAL FOR CHILDREN

MADRAS MEDICAL COLLEGE

CHENNAI

MAY 2018

CERTIFICATE

This is to certify that the dissertation titled **GLYCEMIC CONTROL IN CHILDREN WITH TYPE 1 DIABETES MELLITUS- PREDICTORS AND IMPLICATIONS** submitted by **Dr.Asmita Chandramohan** 2015-2018 session at Madras Medical College to the Faculty of Paediatrics, The Tamilnadu Dr.Mgr Medical University, Chennai, in partial fulfilment of the requirements for the award of M.D. Degree in Paediatrics (branch VII) is a bonafide research work carried out by her under our direct supervision and guidance.

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DECLARATION

This dissertation entitled **GLYCEMIC CONTROL IN CHILDREN WITH TYPE 1 DIABETES MELLITUS- PREDICTORS AND IMPLICATIONS** is a bonafide work done by **Dr ASMITA CHANDRAMOHAN** at Institute of Child health Madras medical college Chennai during the academic year 2015-2018 under the guidance of Prof **Dr.REMA CHANDRAMOHAN MD., DCh,** Professor of Pediatrics, Institute of Child Health, Chennai 600008. This dissertation submitted to The Tamil Nadu Dr.M.G.R. Medical University, Chennai towards partial fulfilment of the rules and regulations for the award of M.D Degree in Paediatrics, Branch (VII)

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I , Dr.ASMITA CHANDRAMOHAN, solemnly declare that the dissertation titled "**GLYCEMIC CONTROL IN CHILDREN WITH TYPE 1 DIABETES MELLITUS- PREDICTORS AND IMPLICATIONS** has been prepared by me under the guidance and supervision of Prof. Dr. Rema Chandramohan MD.,DCh,.

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SPECIAL ACKNOWLEDGEMENT

My sincere thanks to **Prof.R.Narayana Babu, MD., DCH.,** Dean, Madras Medical College, for allowing me to do this dissertation and utilize the institutional facilities.

ACKNOWLEDGEMENT

- It is with immense pleasure and privilege, that I express my heartfelt gratitude, admiration and sincere thanks to **Prof. Dr. T. Ravichandran** M.D,DCh., Director and Superintendent ,ICH and HC for his guidance and support during this study.
- I am greatly indebted to my guide and teacher, **Prof. Dr.Rema Chandramohan, MD, DCH, DNB., PGDDN, PhD** ., Professor of Paediatrics for her supervision, guidance and encouragement while undertaking this study.
- I am immensely grateful to **Dr. Sridevi A Naaraayan** and **Dr. R.V. Dhakshayani** ,Asst professor of paediatrics, Diabetic clinic, Institute of Child Health &Hospital for Children, MadrasMedical College Hospital, for their support, encouragement and suggestions throughout the study.
- I would like to thank my Assistant Professors **Dr. Srinivasan, Dr.M.Karthikeyan, and Dr.Thenmozhi** for their valuable suggestions and support.
- I am extremely thankful to **Dr.Srinivasan .S,** Medical Registrar, for his valuable suggestions and guidance during the study.
- I also thank all the members of the Dissertation Committee for their valuable suggestions.
- I would also like to thank the Diabetic patients attending the diabetic clinic for their active participation without which this study wouldn't have been possible.
- I also express my gratitude to all my fellow postgraduates for their kind cooperation in carrying out this study and for their critical analysis.

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To
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Dear Dr.Asmita Chandramohan.

The Institutional Ethics Committee has considered your request and approved your study titled **"GLYCEMIC CONTROL IN CHILDREN WITH TYPE I DIABETES MELLITUS – PREDICTORS AND IMPLICATIONS" NO. 14102016.**

The following members of Ethics Committee were present in the meeting hold on **04.10.2016** conducted at Madras Medical College, Chennai 3

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11.Tmt.Arnold Saulina, MA.,MSW.,	:Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

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This is to certify that the dissertation work titled **GLYCEMIC CONTROL IN CHILDREN WITH TYPE 1 DIABETES MELLITUS- PREDICTORS AND IMPLICATIONS** of the candidate **DR.ASMITA CHANDRAMOHAN** with registration number 201517012 for the award of **M.D. PAEDIATRICS** in the branch of VII. I personally verified the urkund.com website for the purpose of plagiarism check.I found that the uploaded thesis file contains from introduction to conclusion pages and the result shows 1 percentage of plagiarism in the dissertation

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CONTENTS

INTRODUCTION

Type 1 diabetes mellitus (T1DM) one of the most common chronic diseases in childhood, is caused by insulin deficiency following destruction of the insulin-producing pancreatic beta cells. It most commonly presents in childhood, but about one-fourth of the cases are diagnosed in adults. T1DM remains the most common form of diabetes in childhood, accounting for approximately two-thirds of new diagnoses of diabetes in patients ≤19 years of age in the United States, despite the increasing rate of type 2 diabetes[1-4]. Reliable data on the prevalence and incidence of diabetes in children in India is not available. However it has been found that the incidence is increasing at the rate of 3% per year in European countries.

Diabetes Mellitus is not a single entity, but a group of disorders of varying etiology and pathogenesis. It is a chronic autoimmune disease involving only the beta cells, with gradual loss of insulin secretion. The typical insulin-dependent, ketosis prone patient is classified as having type 1 diabetes. Most children with diabetes present with classical symptoms as will be discussed later. There is no sex predilection and girls and boys may be equally affected.

The disease is associated with a number of short-term and long-term complications many of which are directly linked to the degree of blood glucose levels and their control. Diabetes in childhood and adolescence adversely

affects the growth,development and psychological well-being and must be effectively managed by an entire team of a diabetic nurse/dietician and psychologist in addition to the treating diabetic expert.

RISK FACTORS:

Genetic and environmental factors, both may contribute to the risk of developing type 1 diabetes mellitus[5,6]. In genetically prone individuals, exposure to one or more environmental factors may trigger an auto-immune response that causes destruction of the beta cells of the pancreas. Identification of these factors may lead to an understanding of the pathogenesis of this disease.

There have been reports linking each of the following factors to an increased risk of T1DM; but these associations have been verified and many of them have been contradicted by other studies. They include:

- Viral infections, particularly enterovirus infections
- Immunisations
- Diet(especially exposure to cow's milk at an early age)
- Obesity[7-9]
- Higher Socio-economic status
- Vitamin D deficiency

- Perinatal factors such as maternal age, history of pre-eclampsia and jaundice in the neonatal period. Low birth weight seems to decrease the risk of developing T1DM

CLINICAL PRESENTATION:

Childhood type 1 diabetes mellitus (T1DM) can present in several different ways [10]

- Classic new onset chracterised by chronic polydipsia, polyuria, and weight loss along with hyperglycemia and ketonemia (or ketonuria)

- Diabetic ketoacidosis (DKA onset)

- Silent (asymptomatic) incidental discovery

CLASSIC NEW ONSET

Hyperglycemia without acidosis is the most common presentation of childhood T1DM in most populations. Patients typically present with the following symptoms:

Polyuria

Polyuria occurs when the serum glucose concentration rises significantly above 180 mg/dL,exceeding the renal threshold for glucose, leading on to an increased urinary glucose excretion. Glycosuria causes osmotic diuresis that results in hypovolemia. Polyuria can present as nocturia, bedwetting, or daytime incontinence in a previously continent child.

Polydipsia

Polydipsia is due to enhanced thirst due to the increased serum osmolality from hyperglycemia and hypovolemia. Despite the hypovolemia, patients may not have the classic signs of dry mucus membranes or decreased skin turgor.

Weight loss

Weight loss is again a result of hypovolemia and increased catabolism. Insulin deficiency in diabetic children impairs glucose utilization in skeletal muscle and increases fat and muscle breakdown. Initially, the child's appetite may be increased, but over time, children can get more thirsty than hungry. Ketosis leads to nausea and anorexia, contributing to the weight loss.

Patients with these classical symptoms usually present to the outpatient setting appearing slightly ill, with vague complaints, such as weight loss and lethargy [(11).] The classic symptoms of polyuria and polydipsia are present in more than 90 percent of patients, but these are not always the initial complaints and may become apparent only after obtaining a careful history Weight loss is a presenting symptom in almost half of the children.

Other presentations may include perineal candidiasis, which is a relatively common presenting symptom in young children especially girls . Visual disturbances are common because of alterations in the osmotic milieu of the lens, and to a lesser extent the aqueous and vitreous humors leading to changes in refractive index.[(12)] Children with longstanding hyperglycemia may present with cataracts rarely[(13,14).]

Diabetic ketoacidosis

Diabetic ketoacidosis (hyperglycemia plus ketoacidosis) is the second most common form of presentation for T1DM in most children. Symptoms

may be similar to but are usually more severe than those of patients without acidosis. Patients with ketoacidosis may present with a fruity-smelling breath and neurologic findings like drowsiness and lethargy in addition to polyuria, polydipsia, and weight loss. DKA may be misinterpreted as an acute vomiting illness because the classic pediatric symptoms of dehydration (decreased urination) are masked by the polyuria that is associated with glycosuria.

The reported frequency of diabetic ketoacidosis (DKA) as the initial presentation for childhood T1DM is approximately 30 percent, but can vary from 15 to 67 percent [15,16] Young children (<six years of age) or those from an adverse socioeconomic background are more likely to have DKA as their initial presentation of T1DM.

Children with DKA require hospitalization, rehydration, and insulin replacement therapy. Initial lab evaluation should include blood sugars, bloor or urine ketones, serum sodium, potassium,chloride, bicarbonate,calcium,phosphorous, an arterial blood gas analysis, electrocardiography, blood culture and urine microscopy. It is preferable to catheterize the blader in comatose patients.

Silent presentation

Some children may be diagnosed with T1DM before the onset of clinical symptoms. It is the least common presentation and typically occurs in children who have another close family member with T1DM and are being

closely monitored. The diagnosis is often made by either a family member or clinician with a high index of suspicion. Children with an affected close family member also may undergo pancreatic autoantibody screening to assess risk for the disease although this is not a clinical care recommendation The diagnosis is made based upon an elevated blood glucose concentration using the criteria as discussed below.

DIAGNOSIS

Type 1 diabetes mellitus (T1DM) is one of several different types of diabetes mellitus. The initial step is to diagnose diabetes for which certain criteria have been laid down.[17,18]

DIAGNOSTIC CRITERIA FOR DIABETES

Diabetes mellitus is diagnosed based upon one of the following four signs of abnormal glucose metabolism

- Fasting plasma glucose ≥126 mg/dL (7 mmol/L) on more than one occasion.(where fasting is defined as no caloric intake for at least eight hours)

- A random venous plasma glucose ≥200 mg/dL (11.1 mmol/L) in a patient with classic symptoms of hyperglycemia.
- Plasma glucose ≥200 mg/dL (11.1 mmol/L) measured two hours after a glucose load of 1.75 g/kg (maximum dose of 75 g) in an oral glucose tolerance test (OGTT). Most children and adolescents are symptomatic

and have plasma glucose concentrations well above ≥200 mg/dL (11.1 mmol/L); thus, OGTT is seldom necessary to diagnose T1DM in children

- Glycated hemoglobin (A1C) ≥6.5 percent (using an assay that is certified by the National Glycohemoglobin Standardization Program). (This criterion is more useful to diagnosis of type 2 diabetes mellitus (T**2**DM) in adults, and should be confirmed by hyperglycemia.)

Based upon the guidelines of the American Diabetes Association (ADA), these diagnostic criteria resemble those used in adults with diabetes mellitus. Unless unequivocal symptomatic hyperglycemia is present, the diagnosis **should be confirmed** by repeat testing.

THE ROLE OF HBA1C:

A1C measures the percent of hemoglobin A bound to glucose via non-enzymatic glycation.

It indicates the average blood sugar levels for 10 to 12 weeks before the time of measurement. An A1C ≥6.5 percent is now an accepted criterion for diagnosis of diabetes in adults.

However, the diagnostic utility of A1C for children is less well established than for adults. A1C values ≥6.5 percent are diagnostic of diabetes in adults, but levels <6.5 percent do not exclude diabetes[19]

In one study from Germany, all children with symptomatic, new-onset T1DM had a glycated hemoglobin ≥6.35 percent, whereas those with transient

hyperglycemia had A1C values ranging from 4.5 to 6.1 percent. This shows that HbA1C is not an ideal tool to measure rapid excursions in blood sugar values which are characteristically seen in children with type 1 diabetes but rather a chronic measure of the control of blood sugar level over 10-12 weeks

Individuals with abnormal hemoglobins or rapid destruction of red blood cells may have a measured A1C value that does not accurately reflect the average blood sugar values of the patients. The accuracy of these measurements in individuals with abnormal hemoglobins will improve with use of improved techniques for assessing A1C and with standardization of A1C measurements. For example, hemoglobin variants and derivatives interfere very minimally with the commercially available boronate-affinity chromatography technique. However, the rapid turnover of hemoglobin will still affect the reported A1C level. [20]

CARB-COUNTING

BASIC CARBOHYDRATE COUNTING

In the simplest form, the goal of carbohydrate counting is to promote the glycemic control by implementing a consistent pattern of carbohydrate consumption with meals and snacks on a day-to-day basis. Since the carbohydrate intake directly determines postprandial blood sugar, management of carbohydrate consumption and appropriate insulin adjustments for identified quantities of carbohydrate can improve glycemic control. [21]

Caregivers who have been instructed in carbohydrate counting consume a predetermined total amount of carbohydrate at meals and snacks each day, that are calculated in grams of carbohydrate per food portion. The calculated carbohydrate intake is derived from an optimal percentage of total calories from carbohydrates, based on the nutrition goals and the usual eating pattern.

The caregivers need to be comfortable with simple arithmetical computations. Most of them will require specific training in carbohydrate counting, usually by a dietitian, to set appropriate meal and snack targets and learn to measure or estimate portion sizes and read food labels.

For example, this is a sample of the handouts given to the caregivers while enrolling them into the study (in English or the local language- as per their convenience). They were asked to adhere to this and to maintain a record of it and changes in the glycemic control were studied.

FOOD ITEM	QUANTITY		ON SPILT MIX	ON BASAL BOLUS		
SOUTH INDIAN	CUP/NOS	WT g	EXCHANGE	20-25gm CHO	15 gm CHO	10 gm CHO
BREAD	1	30	1	0.5	1	1.25
IDLI (Small)	1	55	1	0.5	1	1.25
DOSA (Small)	1	50	1	0.5	1	1.25
UPMA/PONGAL/KICHDI	1/3 CUP	80	1	0.5	1	1.25
IDIYAPPAM	1	30	1	0.5	1	1.25
APPAM (Small)	1	45	1	0.5	1	1.25
POORI (Small)	1	30	1	0.5	1	1.25
PARATHA (Small)	1	35	1	0.5	1	1.25
ADAI (Small)	1	45	1	0.5	1	1.25
CHAPATHI (Small)	1	30	1	0.5	1	1.25
RICE/ BIRYANI	1/3 CUP	80	1	0.5	1	1.25
SAMBAR	¾ CUP	180	1	0.5	1	1.25
SUNDAL	1/3 CUP	55	1	0.5	1	1.25
VADA	2	45	1	0.5	1	1.25
POTATO	1	75	1	0.5	1	1.25
CORN	1/3 CUP	60	1	0.5	1	1.25
YAM	1/3	55	1	0.5	1	1.25
SWEET POTATO	1/3	55	1	0.5	1	1.25
TAPIOCA	¼	40	1	0.5	1	1.25
MILK	1 ¼	300 ml	1	0.5	1	1.25
CURD	1 CUP	250ml	1	0.5	1	1.25

FOOD ITEM	QUANTITY		ON SPILT MIX	ON BASAL BOLUS		
NORTH INDIAN	CUP/NOS	WT g	EXCHANGE	20-25 gm CHO	15 gm CHO	10 gm CHO
DHOKLA	2	70	1	0.5	1	1.25
ALOO PARATHA (Small)	1	30	1	0.5	1	1.25
METHI PARATHA (Small)	1	30	1	0.5	1	1.25
NAAN	½	30	1	0.5	1	1.25
KILCHA	½	30	1	0.5	1	1.25
KOFTA CURRY	1/3 CUP	70	1	0.5	1	1.25
MOONG DHAL KICHADI	1/3 CUP	80	1	0.5	1	1.25
MASALA POHA	1/3 CUP	45	1	0.5	1	1.25

FOOD ITEM	QUANTITY		ON SPILT MIX	ON BASAL BOLUS		
FRUITS	CUP/NOS	WT g	EXCHANGE	20-25 gm CHO	15 gm CHO	10 gm CHO
APPLE	1	100	1	0.5	1	1.25
BANANA	1	60	1	0.5	1	1.25
CHERRIES	16	110	1	0.5	1	1.25
CUSTARD APPLE	1big	65	1	0.5	1	1.25
DATES	2 to 3	20	1	0.5	1	1.25
FIGS, dried	1 ½	25	1	0.5	1	1.25
GRAPES	25	115	1	0.5	1	1.25
GUAVA BIG	1	135	1	0.5	1	1.25
JACK FRUIT	2 MEDIUM	65	1	0.5	1	1.25
KIWI	1	90	1	0.5	1	1.25
LYCHEES	9	90	1	0.5	1	1.25
MANGO	1/3 CUP	90	1	0.5	1	1.25
WATERMELON	1 CUP	220	1	0.5	1	1.25
ORANGE, MEDIUM	1	130	1	0.5	1	1.25
PAPAYA	½ CUP	160	1	0.5	1	1.25
PEAR, MEDIUM	½	85	1	0.5	1	1.25
PINEAPPLE	¾ CUP	120	1	0.5	1	1.25
PLUMS, MEDIUM	2	100	1	0.5	1	1.25
SAPOTA, MEDIUM	1	70	1	0.5	1	1.25
STRAWBERRIES	1 ¼ CUP	190	1	0.5	1	1.25
POMEGRANATE, SMALL	1	100	1	0.5	1	1.25

Carb counting helps to:

●Choose the right amount of insulin to administer before meals and snacks – The insulin dose depends on different factors, including what the child eats (especially the amount of carbohydrates) and how much he or she exercises.

●Plan the child's meals and snacks for the day – the caregiver can use carb counting to figure out how many carbohydrates the child should eat at each meal and snack.

●helps to keep the blood sugar level under control – Spreading out the carbohydrates the child eats over a whole day can help keep his or her blood sugar from getting too low or too high. Eating about the same amount of carbohydrates every day also helps. This can help control the child's diabetes better and prevent medical problems that diabetes can cause.

COMPLICATIONS OF TYPE 1 DIABETES MELLITUS

HYPOGLYCEMIA

A mismatch between the insulin use on one hand and physical activity and meals on the other can result in dangerous hypoglycaemia quite frequently in the life of a child with type 1 diabetes

Defined as a value less than 60mg/dl it is heralded by adrenergic symptoms like sweating, pallor, trembling and tachycardia. Patients are taught to recognize these symptoms and treat the child accordingly. If unrecognized, blood sugar values may further drop leading to neurological symptoms suggestive of neuroglycopenia like drowsiness, confusion,coma or seizures.

LONG TERM COMPLICATIONS

They can be grouped into two major categories

- **MICROVASCULAR**
- **MACROVASCULAR**

MICROVASCULAR COMPLICATIONS:

These primarily affect the eyes, kidneys and nerves and can result in retinopathy, nephropathy and neuropathy respectively.

MACROVASCULAR COMPLICATIONS:

Include cerebrovascular and coronary artery disease- both of which are not commonly seen in the pediatric population.

Other complications include:

- Poor growth
- Hypertension
- Eating disorders
- Psychiatric issues- most commonly depression

MANAGEMENT OF TYPE 1 DIABETES:

There are certain unique challenges in caring for children and adolescents with diabetes that differentiate pediatric from adult care.

These include the obvious differences in the size of the patients, developmental issues such as the unpredictability of a toddler's dietary intake and activity level and inability of the toddler to communicate the symptoms of hypoglycemia, and medical issues such as the increased risk of hypoglycemia and diabetic ketoacidosis (DKA). Because of these considerations, the management of a child with type 1 diabetes must take into account the age and developmental maturity of the child.[22]

Insulin therapy happens to be the mainstay of treatment for type 1 diabetes mellitus. The goal of insulin therapy is to replace the deficient hormone in these affected individuals and to attain normoglycemia. This goal, however, remains elusive because of the difficulty in replicating the minute-to-minute variations of physiologic insulin secretion as in normal individuals and the difference in delivery of exogenous insulin action compared with normal

secretion of endogenous insulin directly into the portal vein. The acute and chronic complications of diabetes are attributable to the failure of exogenous insulin to completely mimic physiologic insulin secretion.

There are many different insulin preparations and delivery systems available for use.A selected regimen is individualized for the child and family to fit their lifestyle and optimize compliance while providing glycemic control. Input from the patient, if age appropriate, and the family (that is, timing of meals and snacks, school/daycare, physical activity) is important to ensure optimal glycemic control and minimize episodes of hypoglycemia. As a result of these wide variations, the types of insulin and regimens used will vary among children and can change for the same individual over time.

REVIEW OF LITERATURE

1. Stuart A Chalew and his colleagues studied the pediatric diabetic patients visiting the diabetic clinic at New Orleans and it was found that longer duration of diabetes was associated with higher hemoglobin A_{1c} . The effect of race (African American vs. Caucasian) on hemoglobin A_{1c} was independent of the influence of sex, insurance status, body mass index (BMI) *z*-score, and the number of clinic visits. It was concluded that poorer glycemic control of African-American children as compared to the Caucasian children is likely to predispose them to a higher likelihood of developing microvascular complications as they age. They found that standard hospital-based multidisciplinary programming for diabetes management may have limited effectiveness in improving glycemic control of African-American children with diabetes. Innovative intervention programs were suggested for these high-risk patients. [(23)]
2. Hanaa A Mohammad and his colleagues conducted a study at the Pediatric department , Assiut University, Assiut, Egypt. 415 children aged 2 to 18 years with type 1 diabetes of >1-year duration were enrolled into the study and were subjected to full history including demographic factors and disease-related factors. Examination was done with determination of the body mass index, and assessment of stage of maturity. Investigations included hemoglobin A1c (HbA1c) and lipid

profile. Patients with HbA1c above the recommended values for age by the American Diabetes Association were considered as poor glycemic control group. Of the studied cases, 190 cases (45.8%) had poor glycemic control. Patients with poor control had significantly higher mean age (16.83 ± 3.3 *vs* 9.77 ± 3.7, *P*<0.000). Girls aged 15 years or more had poor glycemic control compared to the males of the same age group. Looking at the disease-related factors, patients with poor control had significantly longer duration of disease (7.94 ± 2.6 *vs* 2.40 ± 2.0, *P*<0.000) and had a higher age at onset of disease. It was concluded that duration of diabetes more than 5 years, and high serum triglyceride level are the predictors of poor glycemic control of children with T1DM in Assiut - Egypt. And it was emphasized that pediatricians need to be aware of factors associated with poor glycemic control in children with T1DM, so that effective measures can be implemented to prevent deterioration in diabetes control .[24]

3. A study published in the ISPAD journal in May 2017 studied a total of 17,□915 articles which were identified from 6 databases and 20 studies were finally included in the analysis. The children who were included in the study were those who had type 1 diabetes diagnosed less than a year. Significant predictors of poorer glycemic control 0 to 3□months after diagnosis were older age and female gender. Non-white ethnicity, diabetes autoantibody positivity, measures of deprivation, and non-private health insurance were potential predictors. Predictors of poorer

glycemic control 4 to 12 months after diagnosis were found to be older age, non-white ethnicity, a single parent family, high hemoglobin A1c (HbA1c) levels at diagnosis, longer T1DM duration, and non-intensive insulin therapy. Potential predictors included family with health issues, clinical factors, and comorbidities at diagnosis. Most significant predictors of poor glycemic control within 12 months of diagnosis of childhood onset T1D were found to be non-modifiable. It was advised that these factors need to be recognized and addressed through individualized and multidisciplinary diabetes care and that further research is required to confirm the association of potential predictors with early glycemic control.[25]

4. An observational study was done on 173 children by S. Shalitin et al at The Jesse Z and Lea Shafer Institute of Endocrinology and Diabetes, National Center for Childhood Diabetes , Schneider Children's Medical Center of Israel. Factors that predict glycemic control in children diagnosed with type 1 diabetes before 6.5 years of age were analyzed in the study. Factors significantly predicting achievement of the mean target HbA1c <7.5% were lower HbA1c at 0.5 years and 1 year after the diagnosis of diagnosis ($P = 0.002$ and $P < 0.001$, respectively). Their results suggest, that in patients with T1D diagnosed during the preschool-age, mean HbA1c level in the first year is a strong predictor of achieving target HbA1c level in the subsequent years, regardless of the type of insulin regimen. This, they call "metabolic tracking" and it

emphasizes the importance of achieving early optimal control even in younger children.[26]

5. Loveline L. Niba, Benedikt Aulinger, Wilfred F. Mbacham and Klaus G. Parhofer conducted a hospital based cross-sectional study involving 76 children/adolescents (35 boys and 41 girls, mean age of 15.1 ± 3.1 years) with type 1 diabetes. Data on glycosylated hemoglobin (HbA1c) was obtained from the hospital records of participants. Information on socio-demographic characteristics and diabetes related practices were obtained from participants using a structured questionnaire. Odds ratios (OR) were calculated to assess the association between determinants and good glycemic control. The study population had a mean HbA1c of 10.3 ± 2.9%. Bivariate analysis indicated that the mother as the primary caregiver being on 2 daily insulin injections and good blood glucose monitoring (BGM) adherence were significantly ($p < 0.001$) associated with better HbA1c. Minimal/moderate caregiver involvement in BGM and insulin injection were significantly ($p < 0.001$) associated with poor outcome. Multivariate analysis showed that the mother as the primary caregiver was an independent predictor of good glucose control. This study has shown that the mother's involvement in the diabetes management of their children and minimal/moderate caregiver involvement in the task of insulin injection are the most important determinants for good and poor glucose control respectively. However, it is unclear whether the

direct involvement of the mother is causal or whether ‘mother as a primary caregiver’ is just an indicator for a setting in which good diabetic treatment is possible. [27]

6. Stacey L. Urbach et al conducted a study on 155 children attending the diabetic clinic in Portland. Patients' hospital charts were reviewed to determine demographic factors, disease-related characteristics, and HbA1c level. The mean HbA1c was 9.3%. Adolescents between the ages of 14 and 18 yr were in poorer metabolic control. Children with married parents were in better glycemic control than those of single, separated, or divorced parents. This study suggests that adolescents should be targeted for improved metabolic control. The diabetic team members need to be aware of changing family situations and provide extra support during stressful times. Regular clinic attendance is an important component of intensive diabetes management and strategies must be developed to improve accessibility to the clinic and also to identify patients who frequently miss appointments.[28]
7. Sanjeev n. Mehta et al conducted a study in Joslin Diabetes Centre, Boston, on the association between parent carbohydrate counting knowledge and glycemic control in youth with type 1 diabetes. they included children 2–12 years with type 1 diabetes atleast of 1 year duration . They had a daily insulin dose 0.5 units/ kg, used carbohydrate counting in meal planning, and were intensively treated with multiple (three or more) daily injections or insulin pump therapy. A1C was

determined at the study visit. Among intensively treated children with type 1 diabetes, parental carbohydrate counting knowledge was associated with lower A1C. Consistency (precision) when estimating carbohydrate content was associated with improved glycemic control. Future studies investigating factors that promote carbohydrate counting knowledge could help optimize nutrition education for children with type 1 diabetes and their families. [29]

8. A study was carried out by Hossain Moravej et al on 100 children with T1DM who had been referred to a pediatric diabetes subspecialty clinic that was affiliated to Shiraz University, Iran. Inclusion criteria were type I diabetes mellitus definitely diagnosed based on World Health Organization (WHO) definition , children aged between 1 and 18 years of age, and being diagnosed with disease for more than 1 year, to rule out the effect of the honeymoon period. In this study, the only significant factor affecting glycemic control and HbA1C level was the patients' age, older children had higher HbA1C and poorer glycemic control. It may occur due to psychosocial problems such as independence from the family,decreasing physical activities, hormonal changes like high resistance to insulin during puberty and to some extent due to progressive nature of the disease.Based on this study, sex had no effect on glycemic control. [30]
9. In one of the largest diabetic studies carried out by the Diabetes Control and Complications Trial Research Group including Nathan DM et al, a

total of 1441 patients with type 1 Diabetes Mellitus--726 with no retinopathy at base line (the primary-prevention cohort) and 715 with mild retinopathy (the secondary-intervention cohort) were randomly assigned to intensive therapy administered either with an external insulin pump or by three or more daily insulin injections and guided by frequent blood glucose monitoring or to conventional therapy with one or two daily insulin injections. The patients were followed up for a mean of 6.5 years, and the appearance and progression of retinopathy and other complications were assessed regularly. In the primary-prevention cohort, intensive therapy reduced the adjusted mean risk for the development of retinopathy by 76 percent as compared with conventional therapy. In the secondary-intervention cohort, intensive therapy slowed the progression of retinopathy by 54 percent and reduced the development of proliferative or severe nonproliferative retinopathy by 47 percent In the two cohorts combined, intensive therapy reduced the occurrence of microalbuminuria by 39 percent and that of albuminuria by 54 percent and that of clinical neuropathy by 60 percent. However, the chief adverse event associated with intensive therapy was a two-to-threefold increase in severe hypoglycemia. It was effectively concluded that intensive therapy effectively delays the onset and slows the progression of diabetic retinopathy, nephropathy, and neuropathy in patients with IDDM. [31]

10. A retrospective study was carried out at the diabetes clinic for children and adolescents at Zawia Teaching Hospital by Dr Aboulgasem EM Elgerbi . One hundred children and adolescents attending the clinic were enrolled into the study. The mean HbA1c was found to be 11.1 %. Children aged less than 10 years were found to have a significantly better glycaemic control (9.83%) as compared to children aged more than 10(11.46%) . Younger children had better adherence to all treatment modalities and had optimal caregiver involvement in diabetes related tasks. Adherence to insulin injections was better in children who had optimal caregiver involvement in the task of injecting insulin. Younger age and having the mother as the primary caregiver had a significantly lower mean HbA1c as compared to those whose caregivers were a father, a sibling or another family member. It was concluded that children and adolescents with T1DM in the Zawia province have very poor glycemic control. Factors associated with poor control include older age, a caregiver other than the mother and poor compliance with insulin therapy, shortage in insulin supply, poor adherence to BGM, lack of physical activities and regular follow up to diabetic clinic . In order to improve metabolic control, more frequent BGM should be encouraged. It was advised that emphasis needs to be put on adherence counseling and active participation of caregivers in diabetes related tasks of their children and that close follow up of the adolescents is necessary as this group is the most vulnerable to poor control. [32]

11. A study conducted in the Children's medical centre, Tehran university, Iran, by Setoodeh A et al, revealed that girls had a poorer glycemic control compared to boys.In this cross-sectional study, children with T1DM referred to their endocrinology clinic from March 2005 through March 2007 were enrolled and for each patient a questionnaire was filled and the effect of gender on glycemic control was analyzed. It was found that boys monitored their SMBG significantly more than girls. Mean HbA1c was used as an indicator of glycemic control, insulin dose per kg of the body weight, frequency of diabetic ketoacidosis (DKA), height issues and dyslipidemia were significantly higher in the girls.[33]

STUDY JUSTIFICATION

- Various studies have shown multitude of factors responsible for glycemic control in a child with Type 1 DM.
- Such studies are significantly lacking in the Indian setting [34]
- Only if the factors are identified clearly will it be possible to maintain euglycemia which is essential for optimal growth and development for a growing child.

OBJECTIVES OF THE STUDY:

PRIMARY OBJECTIVE:

To identify the predictors of poor glycemic control in type 1 DM children based on demographic and disease related data.

SECONDARY OBJECTIVE:

1. Prevalence of poor glycemic control
2. Morbidities associated with poor glycemic control and effect of carb counting on HbA1c

MATERIALS AND METHODS

SUBJECTS AND METHODS:

- **STUDY DESIGN**: Nested Case Control Study
- **STUDY PLACE**: Diabetic clinic, Institute of child health and hospital for children, Egmore, Chennai- 600008
- **STUDY PERIOD: S**ept 2016 to September 2017
- **STUDY POPULATION:** Children with proven type 1 diabetes mellitus, having the disease for at least one year duration between the age 5 and 15 years

INCLUSION CRITERIA:

- Known type 1 Diabetes Mellitus ,
- At least 1 year duration of the disease
- Age range 5-15 years.

EXCLUSION CRITERIA:

- Those children unwilling to follow-up.

SAMPLE SIZE: 100 (convenient)

ETHICS: Written informed consent was obtained from all parents and institution review board clearance was obtained

CASE DEFINITION:

According to the ISPAD definition, the target HbA1c for all age-groups is a value less than 7.5% (58 mmol/mol) according to which the child is grouped into good glycemic control or poor glycemic control.

MANOEUVRE

After obtaining informed consent from either parent, history shall be obtained from the child regarding the demographic data and disease related characteristics. Anthropometry will be measured and the BMI will be calculated. Blood will be drawn (2ml) for the assessment of HbA1c.

Carb counting, the way to measure carbohydrates and its advantages will be elaborated in detail to the primary caregiver after which, if they agree to do it, a record shall be given to them asking them to maintain the carb count done for every meal for three months.

The caregiver is requested to bring the child after three months for a repeat HbA1c.

The following history will be noted-

Demographic factors:

- Age
- Sex
- Residence
- Family history of diabetes and its degree
- Socioeconomic state of the family
- Birth order
- Primary caregiver
- Educational qualification of primary caregiver

Disease-related characteristics:

- Age at onset of disease
- Duration of the disease
- Child attained puberty or not
- Frequency of blood group monitoring
- Carb-counting done or not
- Frequency of diabetic clinic visits

  Relevant measurements and investigations shall be done
- ANTHROPOMETRY – BMI
- INVESTIGATIONS

  -HbA1c

According to the HbA1c values and serially monitored blood glucose levels the patients are grouped into good glycemic control and poor glycemic control.

STATISTICAL ANALYSIS

- The data was coded and entered in an excel sheet.
- It was processed and analyzed using statistical software SPSS
- Continuous variables were presented as mean ± standard deviation and categorical variables were presented as percentage.
- Each of the factors were compared in children with good glycemic control and poor glycemic control.
- Predictors of poor glycemic control were examined by using multivariate logistic regression.
- For all analyses, p value of <0.05 was considered statistically significant.

OBSERVATIONS AND RESULTS

112 children with type 1 Diabetes were enrolled into the study and dada from these children were used for various analysis and interpretations.

GENDER

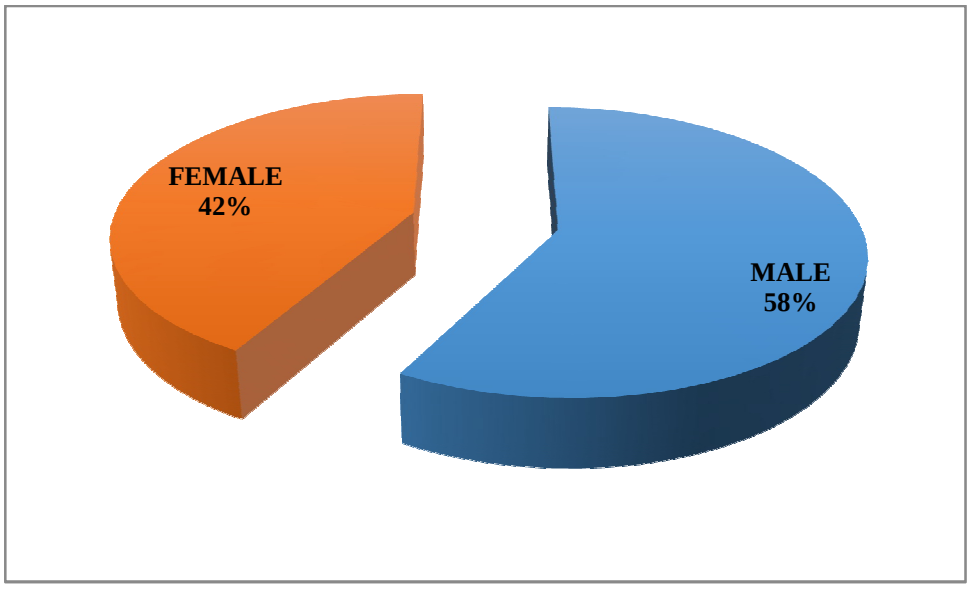


CHART 1: Distribution of gender amongst type 1 diabetic children

This chart depicts the number of females and males enrolled into the study. Out of 112 children 42% were females (47) and 58% were males (65)

BIRTH ORDER

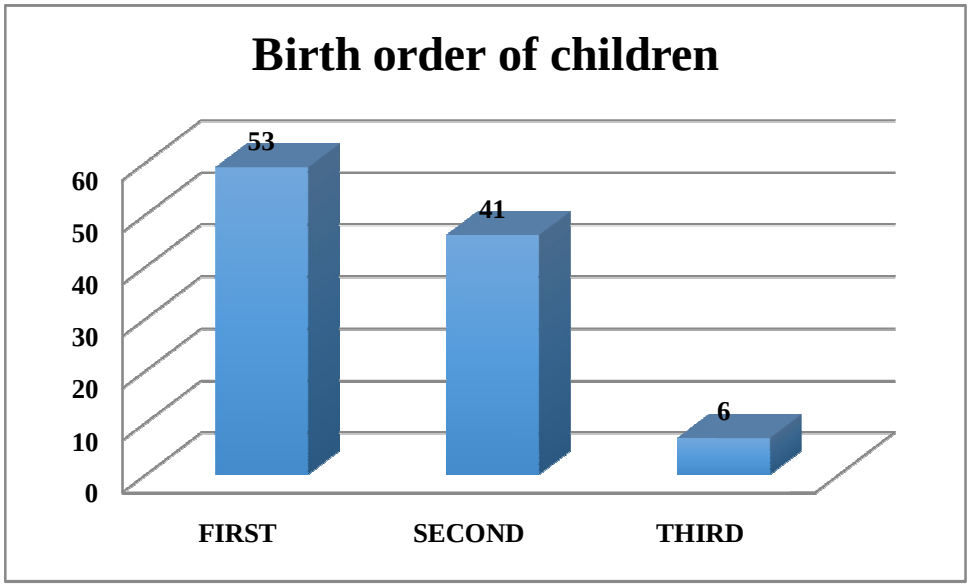


CHART 2 : Birth order of the children enrolled into the study

53% of the children were first born, 41% were second born and the remaining 6% were third born.

RESIDENTIAL AREA

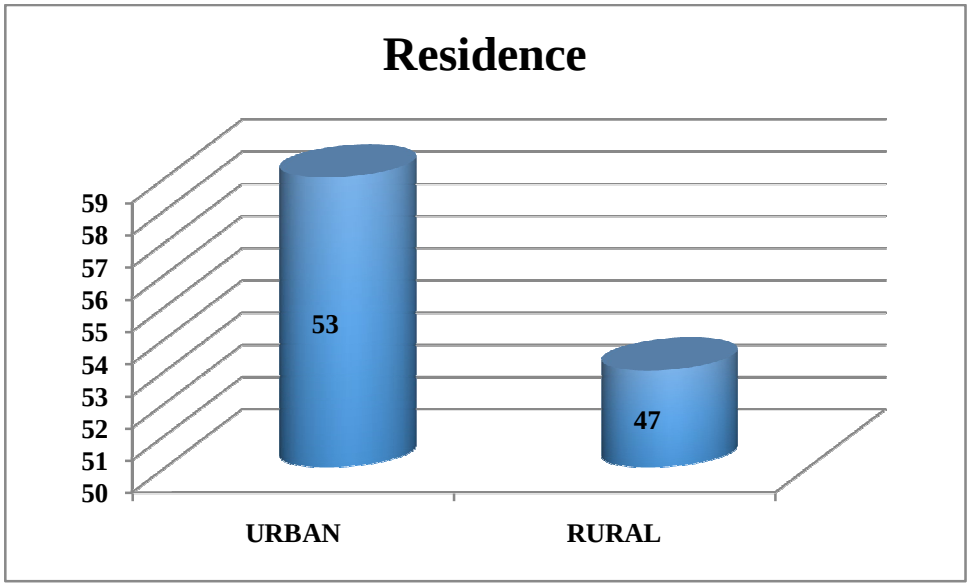


CHART 3: percentage of children residing in urban areas vs rural areas

53% of the children attending the diabetic clinic were hailing from urban areas whereas the remaining 47% resided in rural areas.

FAMILY HISTORY

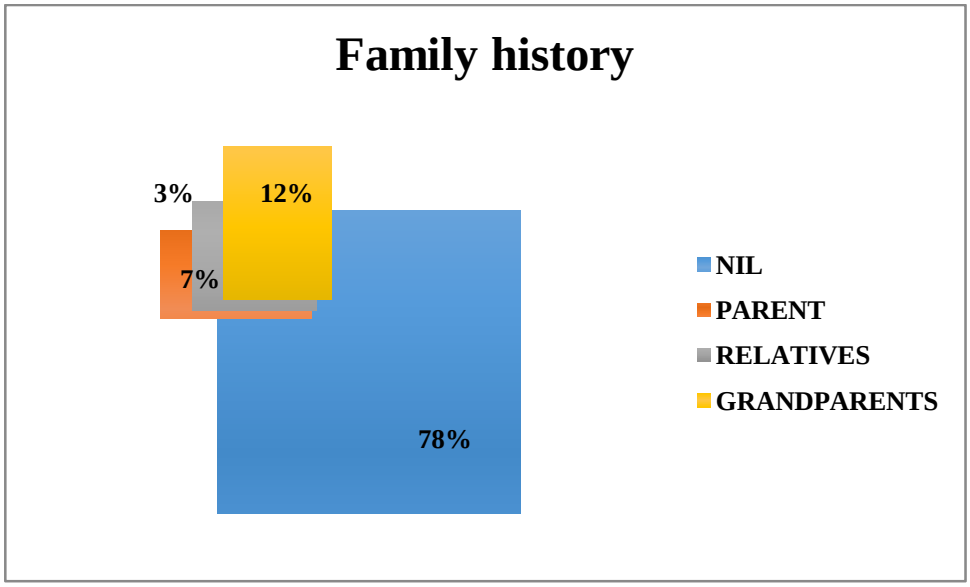


CHART 4: Percentage of children with a family history of diabetes

Out of 112 children, 78% had no family history of diabetes, whereas 12% had atleast one grandparent affected with the disease.

7% children had a first degree relative with the disease whereas 3% had a second degree relative affected by diabetes.

MOTHER'S AGE

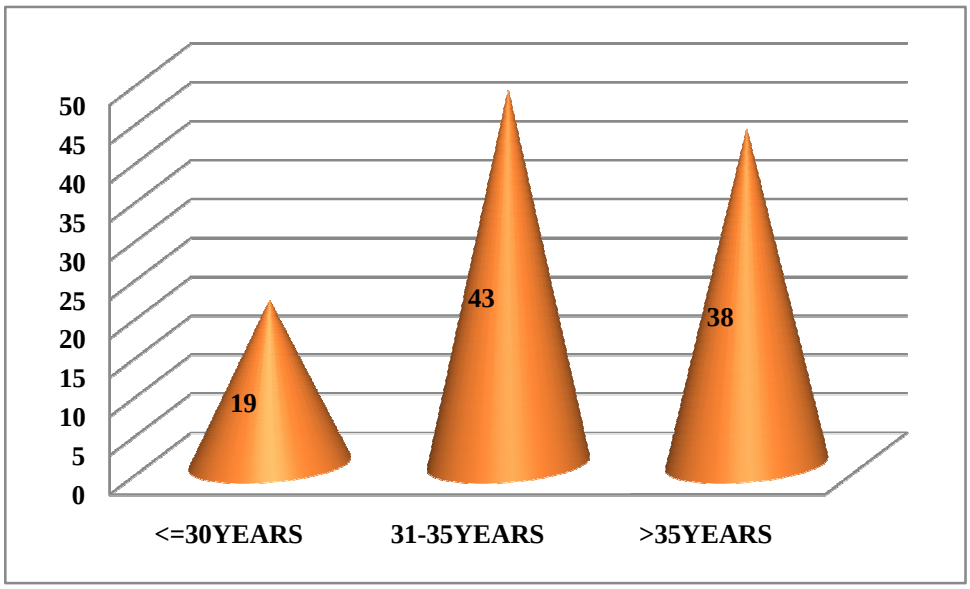


CHART 5: age group of mothers of the diabetic children

19% of mothers were less than 30 years of age whereas the majority - 43% were in the age group 31-35. The remaining 38% of the mothers were above 35 years of age

FATHER'S AGE

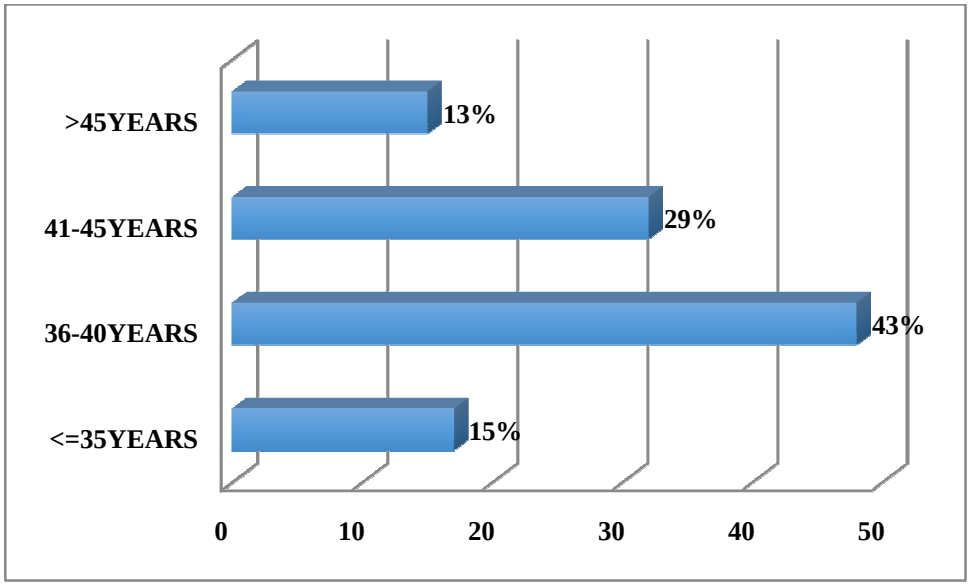


CHART 6: Age group of fathers of the diabetic children

15% of the fathers were below 35 years of age. The majority of the fathers were in the age group of 36-40 (43%). 29% were aged 41-45, whereas the remaining 13% were above 45 years old.

EDUCATIONAL STATUS

MOTHER'S EDUCATION

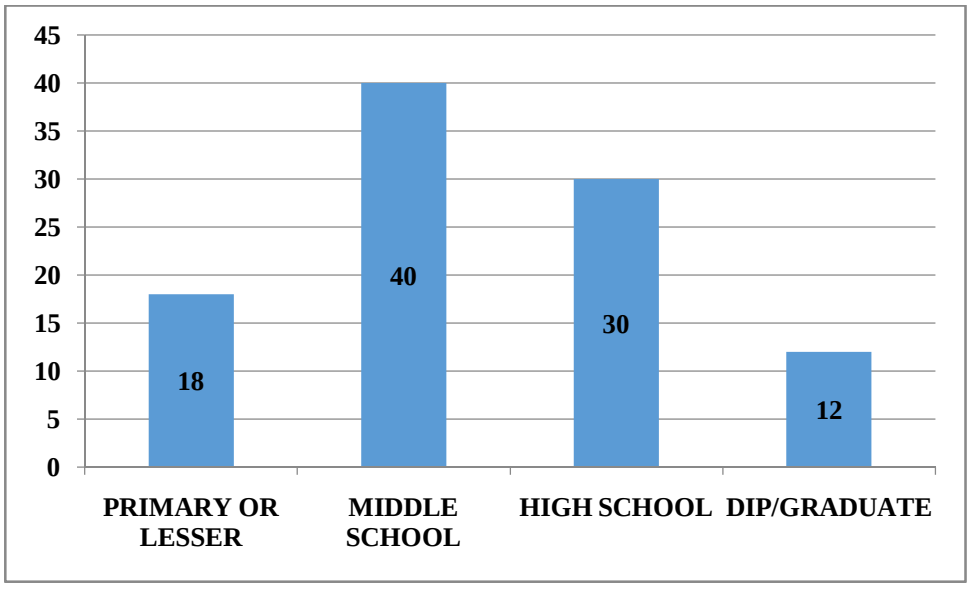


CHART 7: Mother's educational status

Only 9% of mothers had completed a basic degree. 28% completed high school. Majority of the mothers had only attended upto middle school whereas the remaining 17% had only been to primary or were illiterate.

FATHER'S EDUCATIONAL STATUS

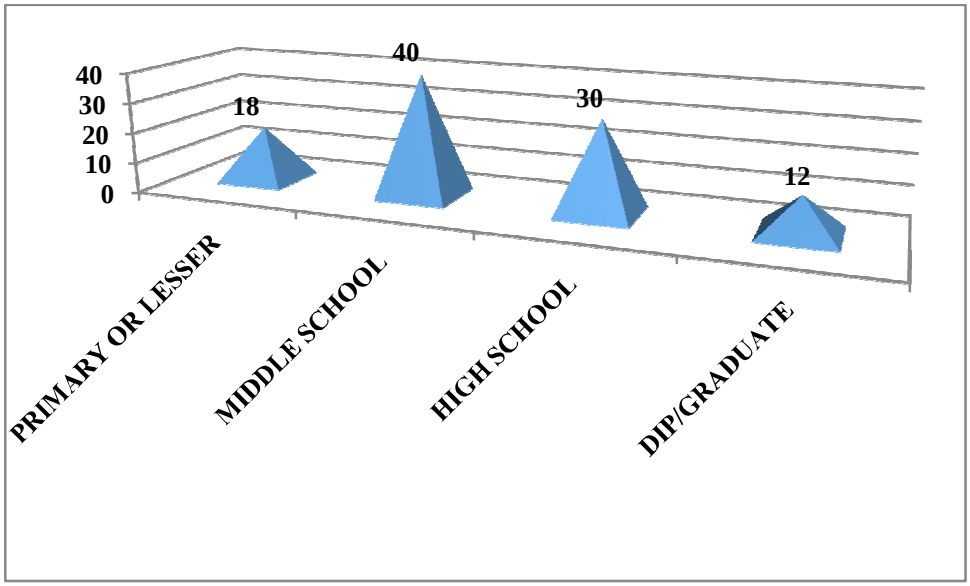


CHART 8: Father's educational status

Only 12% of the fathers had a degree. 18% were illiterate or dropped out of primary school. 30% completed high school whereas the majority of them – 40%- completed middle school.

MOTHER'S EMPLOYMENT

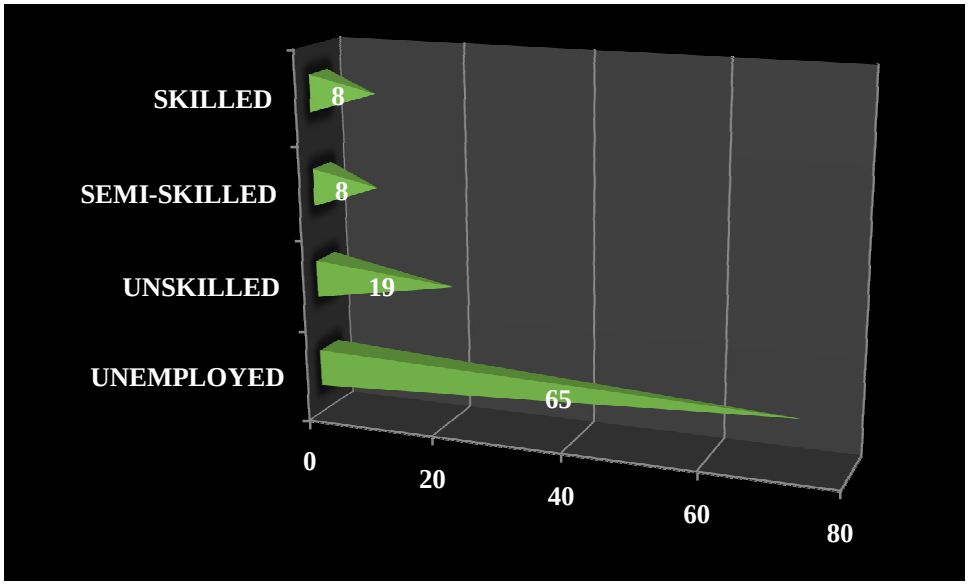


CHART 9: Mother's employment status

65% of the mothers were found to be unemployed. 19% were involved in unskilled labour. 8% were engaged in semi skilled labour whereas 8% were skilled labourers.

FATHER'S EMPLOYMENT

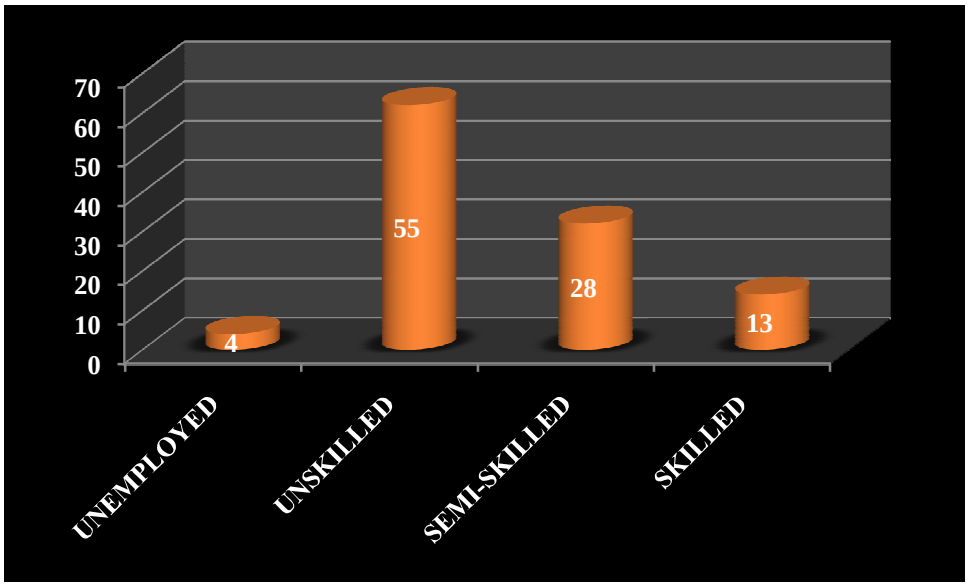


CHART 10: Father's employment status

4% of the fathers were unemployed and 55% were unskilled labourers. 28% were engaged in semi-skilled labour and the remaining 13% were skilled workers.

MONTHLY INCOME

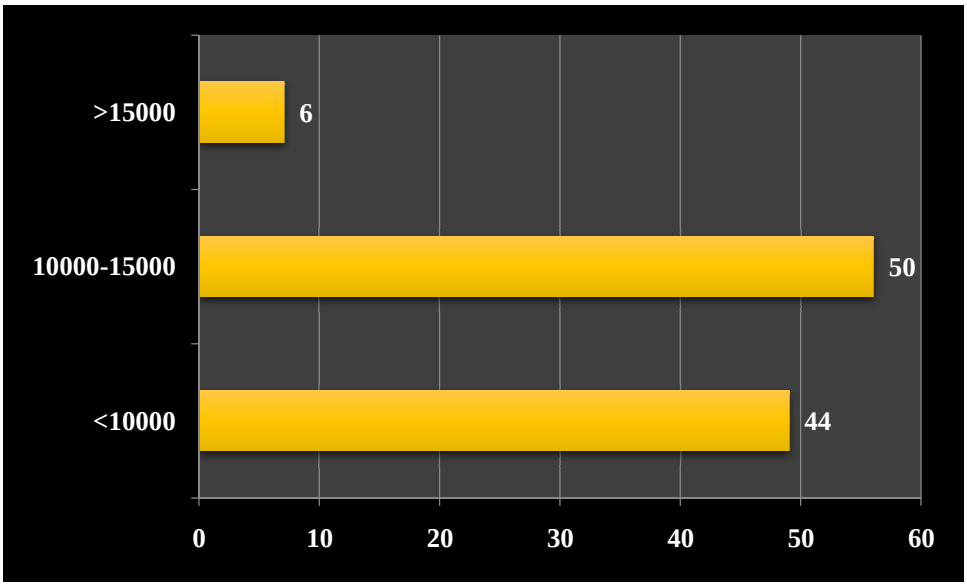


CHART 11: Monthly income of the family

About 6% of the families had an income of >15,000 INR. 50% of the families had a monthly income of 10-15,000 INR. 44% of the families had a monthly family income of less than 10,000 INR.

PRIMARY CARETAKER

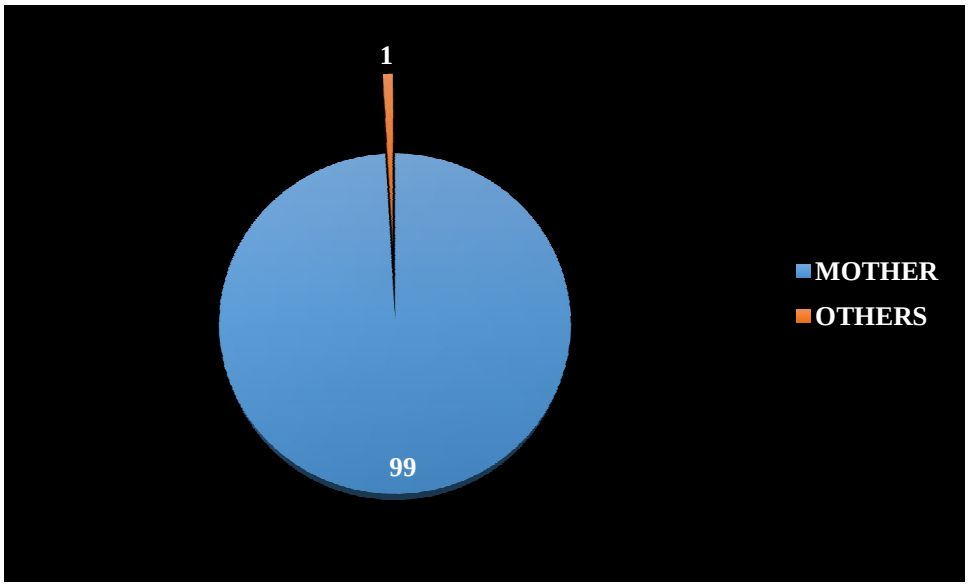


CHART 12: Primary caregiver of the diabetic patient

99% of the children were being cared for by the mothers whereas the remaining 1% were being taken care of by the father/sibling/grandparent.

LIVING WITH PARENTS

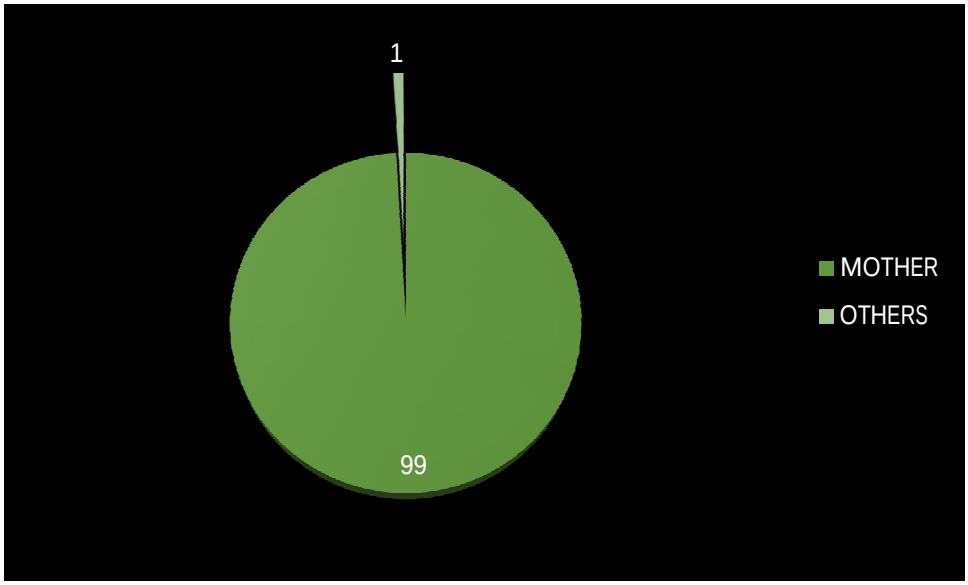


CHART 13: Shows if the child is living with the parents

99% of the diabetic children were found to be living with the parents whereas the remaining 1% were staying with their grandparents.

AGE AT ONSET

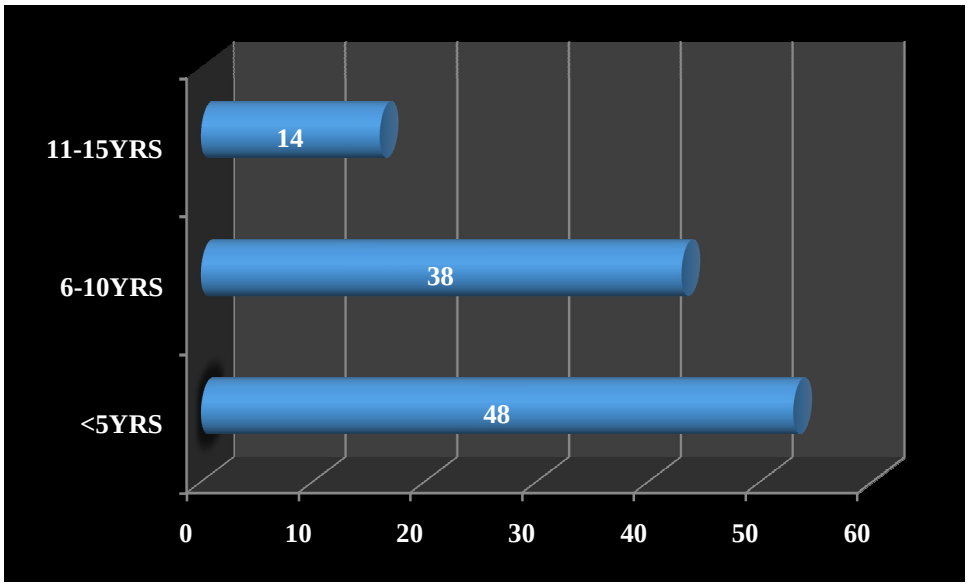


CHART 14: Age at onset of type 1 diabetes

Almost half the patients (48%) presented with diabetes before 5 years of age. 38% presented between the ages 6 and 10. The remaining 14% had an onset between 11 and 14 years of age

DURATION OF DISEASE

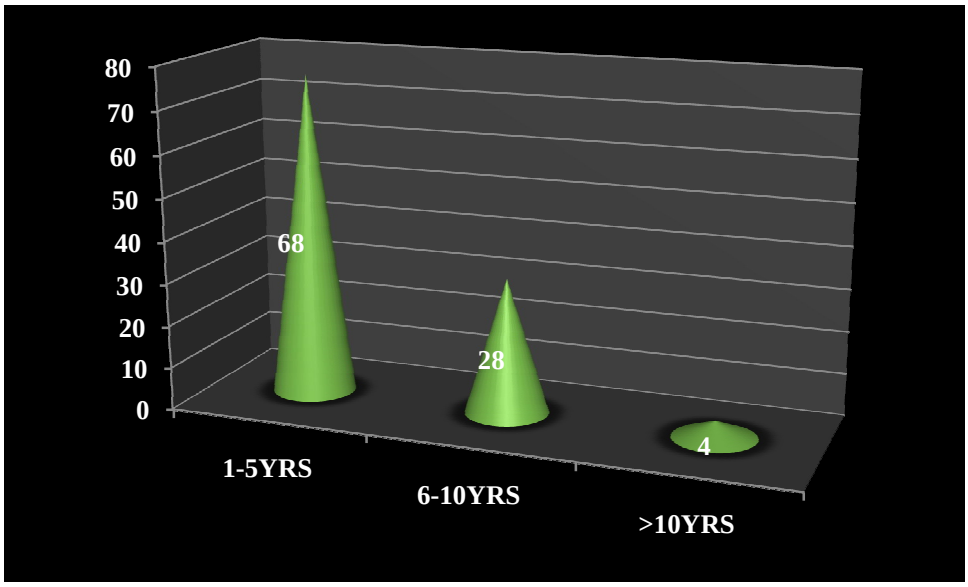


CHART 15: Shows the duration of the disease in the diabetic children

68% were found to have the disease for less than 5 years. 28% were suffering from the disease for the past 6-10 years whereas the remaining 4 % had the disease for over 10 years.

GIRLS WHO HAD ATTAINED PUBERTY

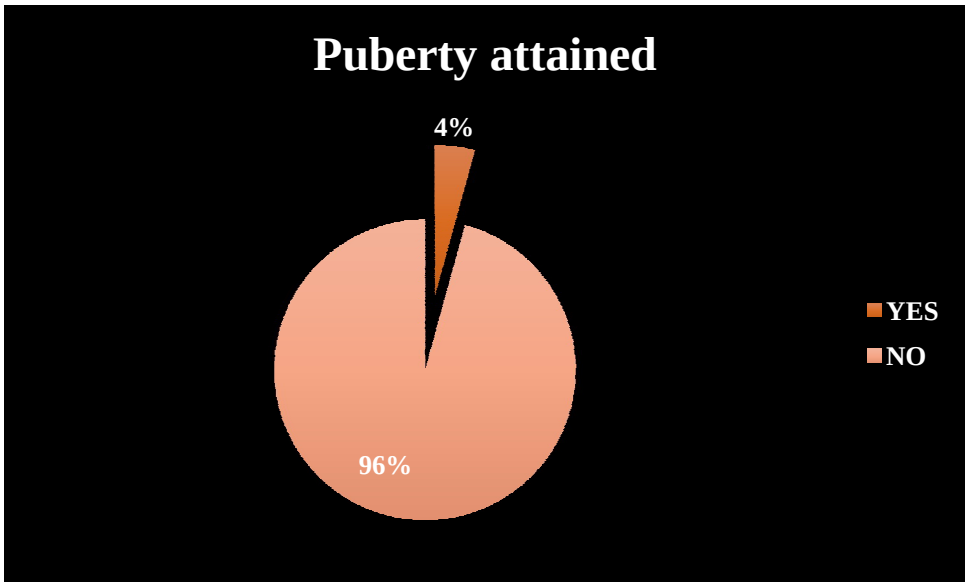


CHART 16: Shows the percentage of girls who had attained puberty

4% of the girls enrolled had attained puberty.

FREQUENCY OF SELF MONITORED BLOOD GLUCOSE MEASUREMENT

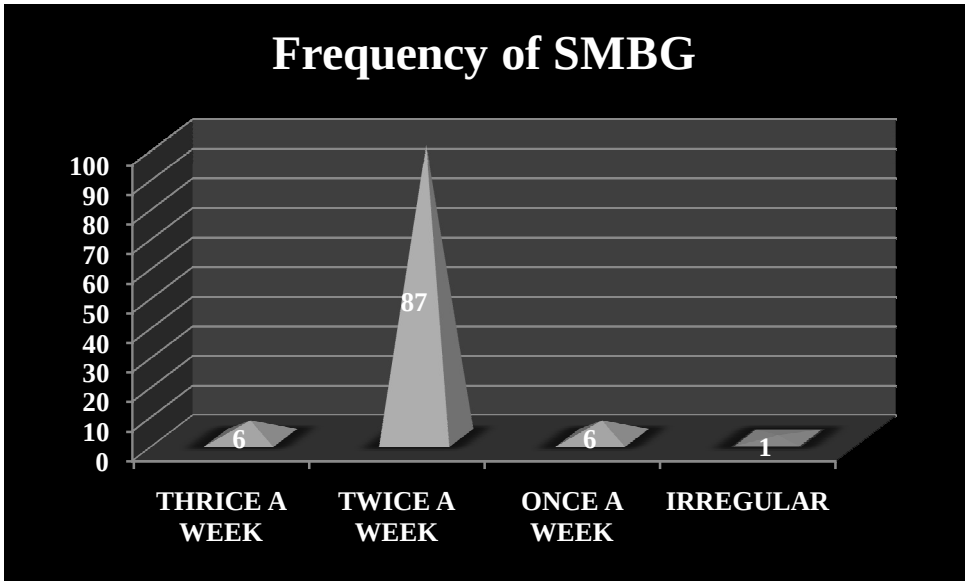


CHART 17: Shows the frequency of self monitored blood glucose measurement

Majority of the patients monitored their blood glucose levels only twice a week (87%) 6 % measured them thrice a week and another 6% once a week. The remaining 1% were found to be measuring the SMBG irregularly.

CARB COUNTING

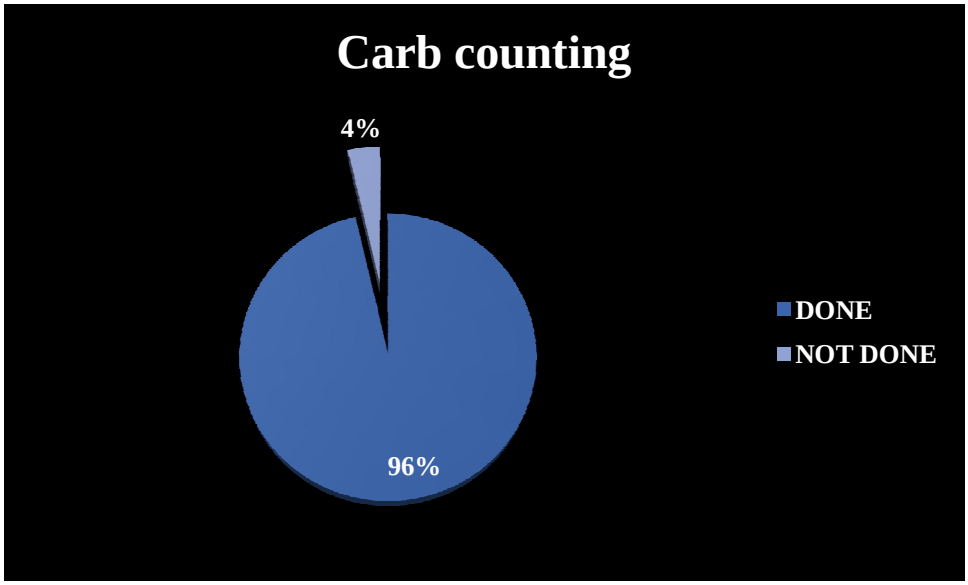


CHART 18: percentage of the diabetic children who had done carb counting

96% of the patients had done carb counting as advised in our diabetic clinic for a time period of three months 4% failed to do so.

FREQUENCY OF DIABETIC CLINIC VISITS

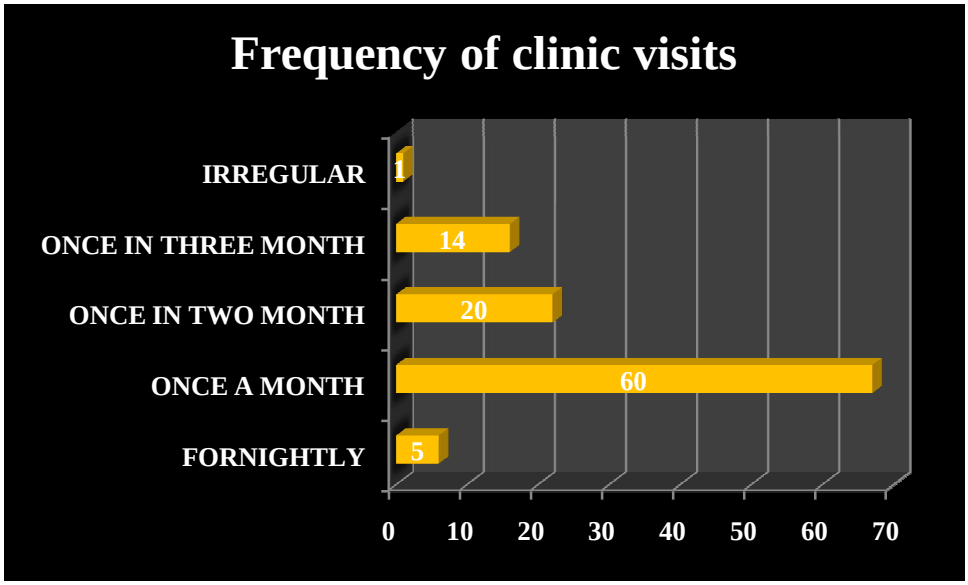


CHART 19: Frequency of clinic visits

5% of the diabetic patients visited the diabetic clinic once in two weeks.

60% of patients visited the only once a month.

20% visited the clinic once in two months and 14% visited once in three months.

Only 1% were found to be irregular.

BODY MASS INDEX OF THE

DIABETIC PATIENTS

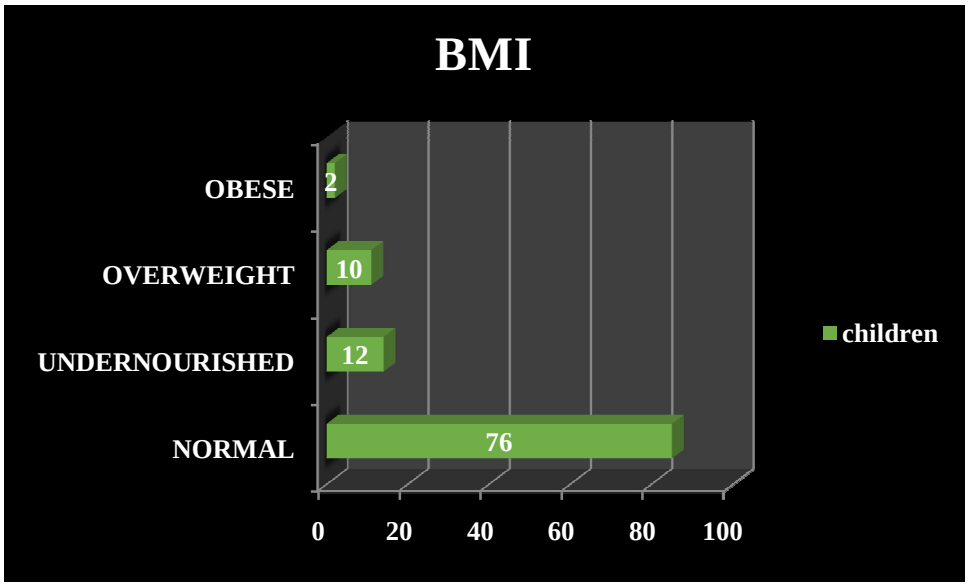


CHART 20: BMI categorised according to percentiles as normal, undernourished, overweight and obese

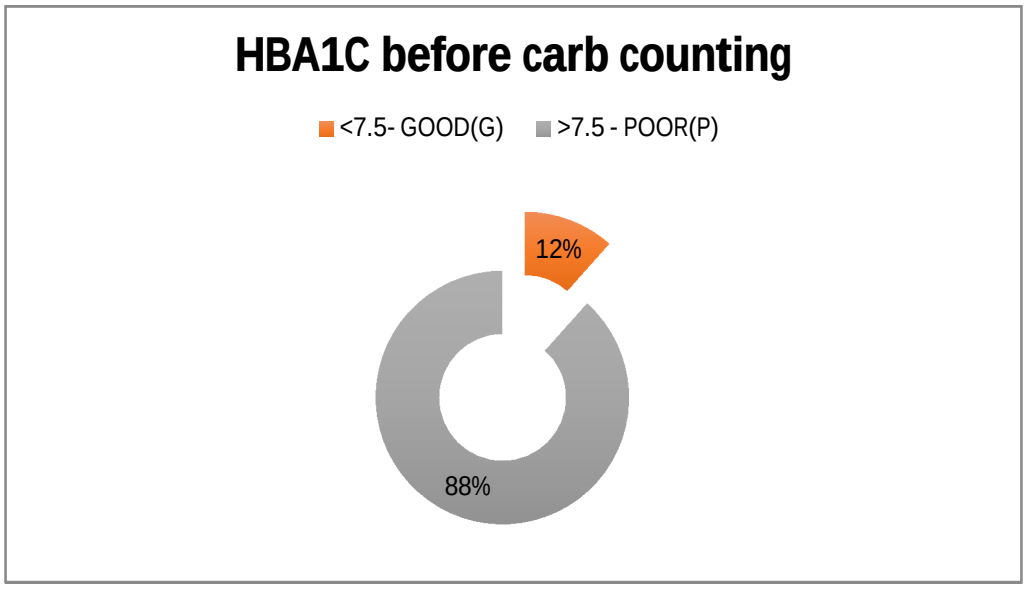
According to the BMI agewise charts children were classified as

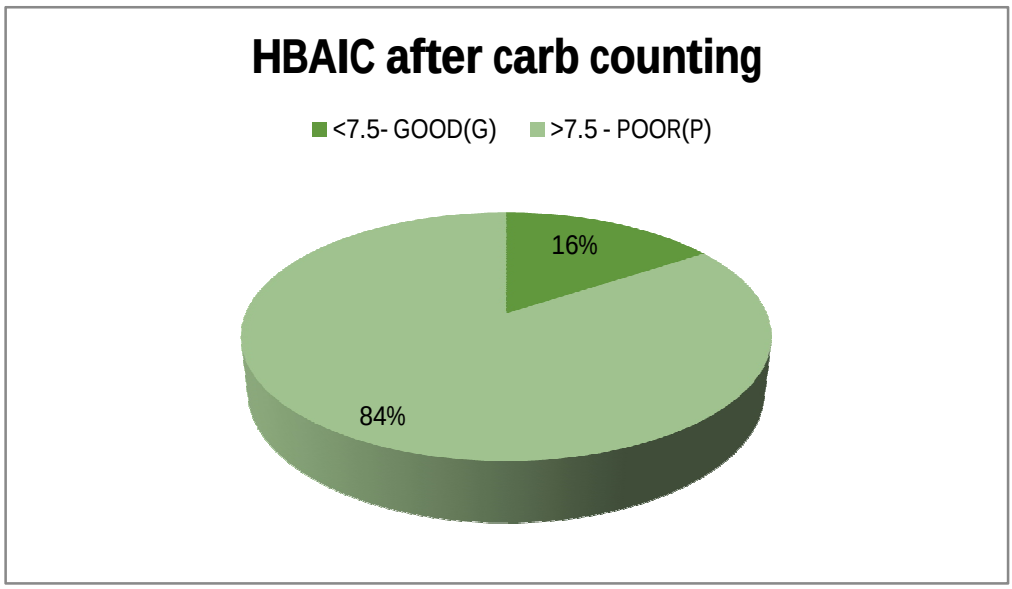
Normal -76%

Undernourished- 12%

Overweight-10%

Obese- 2%





Before carb counting, 12% of the children had a good control and 88% of them had a poor control.

After carb counting it was found that 16% of them had a good control and 84% of them had a poor control.

TABLES

TABLE 1: GENDER AND GLYCEMIC CONTROL

GENDER	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
MALE	7(10.77%)	58(89.23%)	65(100%)	0.745
FEMALE	6(12.77%)	41(87.23%)	47(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

A Chi square test was performed to assess the gender variation with glycemic control.

10.7% males had good control and 89.3% had poor control

12.7% females had good control and 87.3% had poor control

This was not found to be statistically significant.

TABLE 2: BIRTH ORDER AND GLYCEMIC CONTROL

BIRTH ORDER	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
FIRST	4(6.78%)	55(93.22%)	59(100%)	0.275
SECOND	8(17.39%)	38(82.61%)	46(100%)	
THIRD	1(14.29%)	6(85.71%)	7(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

A Chi square test was performed to assess the birth order and glycemic control. 6.7% of first borns had good control, 93.3% had a poor control 17.4% of second borns had good control whereas 82.6% had poor control 14.3% of third borns had good control whereas 85.7% had poor control

This was not found to have any statistical significance

TABLE 3: RESIDENTIAL AREA AND GLYCEMIC CONTROL

RESIDENCE	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
URBAN	5(8.47%)	54(91.53%)	59(100%)	0.165
RURAL	8(15.09%)	45(84.91%)	53(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

Fisher's paired test was done to compare residential area and glycemic control 8.5% of urban children had a good control and 91.5% had a poor control 15% of children coming from rural areas had good control and 85% had poor control. This test was not found to be statistically significant

TABLE 4: FAMILY HISTORY AND GLYCEMIC CONTROL

FAMILY HISTORY	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
NIL	8(9.2%)	79(90.8%)	87(100%)	
PARENT	1(12.5%)	7(87.5%)	8(100%)	
RELATIVES	2(66.67%)	1(33.33%)	3(100%)	0.05
GRANDPARENTS	2(14.29%)	12(85.71%)	14(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

Fisher's paired test was done to compare presence of a positive family history and glycemic control. It was found that 66.7% of patients who had a relative with diabetes had good control and 33.3% of them had a poor control. In patients who did not have any family history 9.2% had good control compared to 90.8% who had poor control

This association was found to be statistically significant.

TABLE 5: MOTHER'S EDUCATION AND GLYCEMIC CONTROL

MOTHER'S EDUCATION	**HBA1C**		**TOTAL**	**P-VALUE¥**
	<7.5- GOOD	**>7.5 - POOR**		
PRIMARY OR LESSER	4(21.05%)	15(78.95%)	19(100%)	0.086
MIDDLE SCHOOL	7(13.46%)	45(86.54%)	52(100%)	
HIGH SCHOOL	0(0%)	31(100%)	31(100%)	
DIP/GRADUATE	2(20%)	8(80%)	10(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the mother's educational status and the effect of glycemic control on the child. 20% graduate mothers had children with good control whereas 80% had poor control

100% of mothers who completed high school had children with poor control 13.5% who had completed middle school had children with good control and 86.5% of them who had completed middle school had poor control 21% of those who had dropped out of primary or were uneducated had children with good control whereas remaining 79% had poor control.

The association was however not found to be statistically significant.

TABLE6: FATHER'S EDUCATION AND GLYCEMIC CONTROL

FATHER'S EDUCATION	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
PRIMARY OR LESSER	4(20%)	16(80%)	20(100%)	0.607
MIDDLE SCHOOL	5(11.11%)	40(88.89%)	45(100%)	
HIGH SCHOOL	3(8.82%)	31(91.18%)	34(100%)	
DIP/GRADUATE	1(7.69%)	12(92.31%)	13(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the father's educational status and the effect of glycemic control on the child.

Only 7.7% graduate fathers had children with good control whereas 88.3% had poor control

8.8% of fathers who completed high school had children with good control and remaining 91.2% had poor control.

11.1% fathers who had completed middle school had children with good control and 88.9% of them who had completed middle school had poor control

20% of those who had dropped out of primary or were uneducated had children with good control whereas remaining 80% had poor control.

The association was however not found to be statistically significant.

TABLE 7: MOTHER'S EMPLOYMENT AND GLYCEMIC CONTROL

MOTHER EMPLOYMENT	**HBA1C**		**TOTAL**	**P-VALUE¥**
	<7.5- GOOD	**>7.5 - POOR**		
UNEMPLOYED	8(10.96%)	65(89.04%)	73(100%)	0.775
UNSKILLED	2(9.52%)	19(90.48%)	21(100%)	
SEMI-SKILLED	2(22.22%)	7(77.78%)	9(100%)	
SKILLED	1(11.11%)	8(88.89%)	9(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the mother's employment status and the effect of glycemic control on the child.

11% of unemployed mothers had children with good control and 89% of them had poor control

9.5% of mothers who were engaged in unskilled labour had good control whereas 90.5% of them had poor control

22.2% of mothers who were engaged in semi-skilled employment had good control whereas 77.8% had poor control

11% of mothers who were in skilled jobs had children with good control whereas the remaining 89% had poor control.

This association was not found to be statistically significant

TABLE 8: FATHER'S EMPLOYMENT AND GLYCEMIC CONTROL

FATHER'S EMPLOYMENT	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
UNEMPLOYED	2(50%)	2(50%)	4(100%)	0.103
UNSKILLED	7(11.29%)	55(88.71%)	62(100%)	
SEMI-SKILLED	3(9.38%)	29(90.63%)	32(100%)	
SKILLED	1(7.14%)	13(92.86%)	14(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the father's employment status and the effect of glycemic control on the child.

50% of unemployed fathers had children with good control and 50% of them had poor control 11.3% of fathers who were engaged in unskilled labour had good control whereas 88.7% of them had poor control 9.4% of fathers who were engaged in semi-skilled employment had good control whereas 90.6% had poor control 7.1% of fathers who were in skilled jobs had children with good control whereas the remaining 92.9% had poor control.

This association was not found to be statistically significant

TABLE 9: MONTHLY INCOME AND GLYCEMIC CONTROL

MONTHLY INCOME	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
<10000	7(14.29%)	42(85.71%)	49(100%)	0.521
10000-15000	6(10.71%)	50(89.29%)	56(100%)	
>15000	0(0%)	7(100%)	7(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the family's monthly income and the effect of glycemic control on the child. 14.3% of those families with family income less than 10,000 INR had good control whereas 85.7% had poor control. 10.7% of families with family income 10,000-15,000 INR had poor control whereas 89.3% had poor control 100% of families with family income more than 15,000 INR had a poor control.

This association was not found to have any statistical significance

TABLE 10: PRIMARY CARETAKER AND GLYCEMIC CONTROL

PRIMARY CARETAKER	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
MOTHER	13(11.71%)	98(88.29%)	111(100%)	0.999
OTHERS	0(0%)	1(100%)	1(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the primary caretaker and the glycemic control of the child. 11.7% of mothers who took care of the children managed to have a good glycemic control whereas 88.3% had a poor control When the child was cared for by someone other than the mother 100% of children had poor control

This association was not found to be statistically significant

TABLE 11: AGE AT ONSET AND GLYCEMIC CONTROL

AGE AT ONSET	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
<5YRS	4(7.55%)	49(92.45%)	53(100%)	0.391
6-10YRS	6(13.95%)	37(86.05%)	43(100%)	
11-15YRS	3(18.75%)	13(81.25%)	16(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the age at onset of the disease and the glycemic control of the child. Only 7.5% of children who had an age of onset <5 years had good control, remaining 92.5% had poor control. 14% of children who had an age of onset between 6 and 10 had good control and the remaining 86% had poor control. 18.8% of children whose onset of disease > 10 years had good control whereas 81.2% of them had poor control.

This association was not found to be statistically significant

TABLE 12: DURATION OF DISEASE AND GLYCEMIC CONTROL

DURATION OF DISEASE	**HBA1C**		**TOTAL**	**P-VALUE¥**
	<7.5- GOOD	**>7.5 - POOR**		
1-5YRS	9(11.84%)	67(88.16%)	76(100%)	0.651
6-10YRS	3(9.38%)	29(90.63%)	32(100%)	
>10YRS	1(25%)	3(75%)	4(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the duration of the disease the glycemic control of the child. Only 11.8% of children who had the disease for less than 5 years had good control, remaining 88.2% had poor control. 9.4% of children who had the disease for 6 to 10 had good control and the remaining 90.6% had poor control 25% of children who were suffering from the disease for more than 10 years had good control whereas 75% of them had poor control.

This association was not found to be statistically significant

TABLE 13: FREQUENCY OF SMBG AND GLYCEMIC CONTROL

FREQUENCY OF SMBG	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
THRICE A WEEK	1(16.67%)	5(83.33%)	6(100%)	0.818
TWICE A WEEK	12(12.12%)	87(87.88%)	99(100%)	
ONCE A WEEK	0(0%)	6(100%)	6(100%)	
IRREGULAR	0(0%)	1(100%)	1(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the duration of the disease the glycemic control of the child.

16.7% of those who monitored their blood glucose thrice a week had a good control

When monitored twice a week 12.1% had good control

Those who monitored their blood glucose once a week or irregularly had 100% poor control.

The association was not found to have any statistical significance

TABLE 14: FREQUENCY OF CLINIC VISITS AND GLYCEMIC CONTROL

FREQUENCY OF CLINIC VISITS	HBA1C		TOTAL	P-VALUE¥
	<7.5- GOOD	>7.5 - POOR		
FORNIGHTLY	0(0%)	6(100%)	6(100%)	0.348
ONCE A MONTH	8(11.94%)	59(88.06%)	67(100%)	
ONCE IN TWO MONTH	1(4.55%)	21(95.45%)	22(100%)	
ONCE IN THREE MONTH	4(25%)	12(75%)	16(100%)	
IRREGULAR	0(0%)	1(100%)	1(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the frequency of clinic visits and the glycemic control of the child. 100% of those who visited once in two weeks as well as 100% of them who were irregular had a poor control. 11.9% who visited once a month had good control whereas 88.1% had poor control. 4.5% who visited once in two months had good control and 95.5% had poor control. 25% of those who visited once in three months had good control vs 75% who had poor control.

The association was not found to have any statistical significance

TABLE 15: BMI AND GLYCEMIC CONTROL

BMI	**HBA1C**		**TOTAL**	**P-VALUE¥**
	<7.5- GOOD	**>7.5 - POOR**		
NORMAL	11(12.94%)	74(87.06%)	85(100%)	0.999
UNDERNOURISHED	1(7.14%)	13(92.86%)	14(100%)	
OVERWEIGHT	1(9.09%)	10(90.91%)	11(100%)	
OBESE	0(0%)	2(100%)	2(100%)	
TOTAL	13(11.61%)	99(88.39%)	112(100%)	

The Chi-Square test was performed to determine an association between the BMI and the glycemic control of the child. 100% of obese children had poor glycemic control. Only 7.1% of undernourished had good control and 92.9% had poor control. 9% of overweight children had good control, 91% had poor control. 13% of children with normal BMI had good control whereas 87% of them had poor control. The association was not found to have any statistical significance

TABLE 16: EFFECT OF CARB COUNTING ON GLYCEMIC CONTROL

HBA1C BEFORE CARB COUNTING	**HBA1C AFTER CARB COUNTING**		**TOTAL**	**P-VALUE¥**
	<7.5- GOOD	**>7.5 - POOR**		
<7.5- GOOD(G)	11(84.62%)	2(15.38%)	13(100%)	0.157
>7.5 - POOR(P)	6(6.32%)	89(93.68%)	95(100%)	
TOTAL	17(15.74%)	91(84.26%)	108(100%)	

To perform this test the McNemar'sChi-Square test was utilised. Majority of the patients who had good control remained the same after they followed carb-counting -84.6% whereas about 15.4% digressed into poor control. Out of those who had poor control, 6.3 % improved and entered into the good control group whereas the remaining 93.7% continued to have poor control

This association was not found to be statistically significant

DISCUSSION

A total of 112 children with type 1diabetes were enrolled into the study and the child's family history, demographic data and disease related data were entered into the proforma. The anthropometry was measured and blood was drawn for HbA1c measurement.

In the first visit- during their enrolment, carb- counting and its importance were explained in detail to the primary caregiver and a record was provided to them to track the child's 'carbs'. When followed –up 3 months later, the record was reviewed and the HbA1c was re-measured to look for any significant change.

All the factors were studied with respect to the glycemic control in the children, where according to the ISPAD definition, values <7.5 were considered to be in good control and values > 7.5 were considered to be in poor control of their sugars.[35]

In the 112 children, the mean HbA1c was found to be 10.8 ± 2.1. Majority of the diabetic patients who presented to us had poor control.

Comparing our study to previously conducted international studies; we tried to find an association between each factor and the glycemic control in these children and also try to find the possible causes for poor control amongst

them so as to help them attain euglycemia and an optimal quality of growth and development in all aspects of life.

Comparing the gender and effect on the glycemic control,10.7% males had good control and 89.3% had poor control whereas 12.7% females had good control and 87.3% had poor control.

The girls seemed to have a slightly better glycemic control compared to the boys enrolled.

This was not in accordance with one of the studies done in Children's Hospital Medical Center, Tehran University of Medical Sciences, Iran where the exclusive effect of gender on glycemic control was studied. It was found that boys monitored their SMBG more frequently than girls and that girls were more prone for dyslipidemia and DKA – worsening their glycemic control. Also, puberty increases the insulin requirement in girls. The probable reasons for a better control in our study were because the girls were more regular in insulin administration and adhered to the SMBG better than the boys. Also, only 4 % of the girls had attained puberty. It can be expected that as more girls grow older they may develop mild insulin resistance due to change in their body fat stores.

In our study 53% of the children were first born, 41% were second born and the remaining 6% were third born. 6.7% of first borns had good control, 17.4% of second borns had good control and 14.3% of third borns had good control

A major study published by Hanaa A. Mohammad et al done in Assuit, Egypt showed that the birth order had no impact on the glycemic control of the child as in our study.

53% of the children attending the diabetic clinic were hailing from urban areas whereas the remaining 47% resided in rural areas. 8.5% of urban children had good control and 91.5% had poor control 15% of children coming from rural areas had good control and 85% had poor control.

Our study shows that the children hailing from rural areas had a better control than the urban children. Though not statistically significant the probable reasons could be because of increased access to junk food in urban areas, lack of physical activity and a sedentary lifestyle in urban children. This was similar to a study conducted in University Children's Hospital in Rio de Janeiro by Verônica Medeiros da Costa et al.

Out of 112 children, 78% had no family history of diabetes, whereas 12% had at least one grandparent affected with the disease 7% children had a first degree relative with the disease whereas 3% had a second degree relative affected by diabetes. 66.7% of patients who had a relative with diabetes had good control and in patients who did not have any family history only 9.2% had good control. However the study done by Hanaa A Mohammed et al in Assuit, Egypt showed that family history had no bearing on the glycemic control of the children. The possible reasons could be the knowledge and

attitude towards the disease in the affected elders, resulting in better compliance by the patients. This was the only parameter that showed statistically significant correlation.

The educational status of either parent or their employment did not seem to influence the glycemic control of the children. This was similar to the other studies, like the study conducted in Egypt by Mohammed et al. The family income too, did not affect the glycemic control in the children.

In 99% of the children, the primary caregiver was the mother. When the child was cared for by someone other than the mother 100% of children had poor control. A study done in North West Region of Cameroon,by Loveline .L. Niba et al showed that the 'mother' being the primary caregiver was an independent factor in good glycemic control in type 1 diabetics. However, if this relationship is causal or just the mere presence of a mother influencing good treatment of diabetes, is still unclear according to them.

Amongst the demographic data, only family history was found to have some significance in affecting the glycemic control in the child.

Coming to the disease related characteristics,

Most of the children who had an age of onset after 10 years had a better control than those with age of onset <10 years. The age of onset does not significantly affect the glycemic control in the children.[36]

While analysing the duration of the disease, 68% were found to have the disease for less than 5 years. 28% were suffering from the disease for the past 6-10 years whereas the remaining 4% had the disease for over 10 years.

Only 11.8% of children who had the disease for less than 5 years had good control, 25% of children who were suffering from the disease for more than 10 years had good control. This was in contrast to the studies done abroad which showed that longer duration resulted in worsening glycemic control owing to the progressive loss in beta cell function of the pancreatic cells. In our set-up, probably, children are entrusted with the SMBG measurements and insulin administration when they have the disease for more than 10 years and when the children grow older they understand the need for self monitoring and the impact of hypoglycaemia and hyperglycemia on their growth and daily functioning.

Carb – counting :

96.5% of the children had done carb- counting whereas 3.5 % had not. But in those children who had done carb counting, majority of the patients who had good control remained the same -84.6%, whereas about 15.4% deteriorated into poor control.

Out of those who had poor control, 6.3 % improved and entered into the good control group whereas the remaining 93.7% continued to have poor control. In a study done by Sanjeev N Mehta et al at Boston University parental knowledge of carb counting was significantly associated with lower HbA1c

values. But in our case, majority of the mothers are uneducated/ primary drop outs and probably were not able to adhere to strict carb-counting. Most of the diabetic children are pampered at home and may also help themselves to snacks without the parents' knowledge which interferes with the carb counting.

Frequency of SMBG measurements :

Majority of the patients monitored their blood glucose levels only twice a week (87%).6 % measured them thrice a week and another 6% once a week. The remaining 1% was found to be measuring the SMBG irregularly.16.7% of those who monitored their blood glucose thrice a week had a good control. When monitored twice a week 12.1% had good control. Those who monitored their blood glucose once a week or irregularly had 100% poor control.

Every study advocates the use of daily glucose monitoring and insulin dose adjustment for the daily values for optimal control, but patients attending our government set up can only afford to do it on a twice weekly basis. This is an area that needs to be worked on in co-operation with the government to provide finances to enable these children to monitor their glucose values every day. This will enable the children to avoid episodes of hypo or hyperglycemia which can adversely affect the quality of life as type 1 diabetes is characterised by marked day-to-day excursions in blood sugar values.[37]

Frequency of clinic visits:

100% of those who visited once in two weeks as well as 100% of them who were irregular had a poor control.11.9% who visited once a month had

good control. 25% of those who visited once in three months had good control. The probable reason for this may be that children with poor control are being followed-up more closely. More frequent visits may be a marker of poor control rather than a cause for it. This is in concordance with a cross-sectional study done by Urbach et al in Oregon Health Sciences University in 2001. [38]

BMI :

According to the BMI age wise charts children were classified as

Normal -76%

Undernourished- 12%

Overweight-10%

Obese- 2%

100% of obese children had poor glycemic control 7.1% of undernourished had good control. 9% of overweight children had good control, 13% of children with normal BMI had good control. BMI did not seem to have a significant impact on the glycemic control of the patients. In the study done in Assuit, Egypt byMohammed et al, it was found that those with low/ normal BMI had higher proportions of good control compared to those with BMI falling in the overweight and obese category. The probable reason has been stated as shorter duration of the disease in these children and younger age of these children. [39]

CONCLUSION

- Of the 112 children enrolled in the study, 47 were females and 65 were males.
- 53% of them were first born, 41% were second born and 6% were third born.
- The gender and the birth order did not contribute significantly as a predictor.
- While 53% were from urban areas, 47% of the children were from rural areas. The children from rural areas were found to have better control, however it was not statistically significant.
- It was found in the study that 78% denied a family history and 22% had an affected close relative.
- Those with a positive family history had a better glycemic control (66.67%) and was found to be a statistically significant predictor of good glycemic control.
- The parents educational status and employment did not impact the glycemic control of the children.
- The socioeconomic status of the affected childrens' families did not correlate significantly with glycemic control.
- Although 99% of the children were living with the parents and the mother was the primary caregiver, this did not ensure good glycemic control.

- 86% had an onset of diabetes before 10 years of age, but the age of onset had no bearing on the glycemic control.
- Those with longer duration of the disease (>10years) seemed to have a better control though not statistically significant.
- Majority of the patients measured the SMBG only twice a week due to logistic reasons.

- Carb counting which was elaborated to the patients after a one to one counselling was followed by 96% of the patients.

- 65% of the patients attended the diabetic clinic once a month. This did not ensure good glycemic control.

- 76% of the patients had a normal BMI. BMI did not statistically correlate with the glycemic control.

- Of those who had done the carb counting, 6.4% of the patients with poor control improved to have a good glycemic control on the repeat hba1c measurement.

LIMITATIONS

- The sample size was limited to 112. A bigger sample size would have yielded better results which would have been more statistically significant.

- HbA1c measurements do not measure the excursions in day to day values of the blood sugars- a characteristic feature of type 1 diabetics and we must look for other predictors of glycemic control as HbA1c is a better predictor of adult diabetes but not type 1 diabetes seen in children.

- Even a fall of HbA1c from 14% to 8% did not show an improvement in the glycemic control from the poor group to the good group due to the arbitrary measurement of 7.5% set by the American Diabetic Association.

- We must probe other ways to categorize the glycemic control instead of a single A1c value of 7.5% , so as to know if there has been any improvement, however minor as compared to the previous values.

- Continous Glucose Monitoring Systems (CGMS) may prove to be a successful way to measure the highly fluctuating blood

glucose levels in a growing child in real time throughout the day and night.[40,41]

- Though expensive it has been proven beyond doubt that it is an effective tool in maintaining euglycemic levels, so that these children may enjoy an optimum quality of life.

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ANNEXURES

ABBREVIATIONS

TIDM- Type 1 Diabetes Mellitus

SMBG - Self Monitored Blood Glucose

HbA1c- Glycosylated hemoglobin

DKA - Diabetic Keto Acidosis

CGMS- Continuous Glucose Monitoring Systems

BMI- Body Mass Index

ISPAD - International Society for Pediatrics and Adolescent Diabetes

ADA- American Diabetes Association

Carb- counting – carbohydrate counting

DATA COLLECTION FORM

Date of filling form –

Name of the child –

Father's name –

Mother's name –

OP number –

Date of birth –

Age-

Sex-

Residence – 1) Urban 2) Rural

Birth order of this child –

Family history of diabetes-

Parents' charecteristics –

S No.	Charecteristic	Mother	Father
1	Age		
2	Education(Use code)		
3	Employment status(Use code)		

Family Income –

Primary caretaker – 1) Mother 2) Father 3) Grand parent 4) Others

Living with parents/not – 1) Living 2) Not living

Codes for parents' education and occupation-

Education	code	Occupation	code	Monthly income	code
Professional / Post graduate	7	Profession	7	>32,050	7
Graduate	6	Semi-Profession	6	16,020 – 32,046	6
Intermediate / Diploma	5	Clerical / Shop / Farm owner	5	12,020 – 16,019	5
High school	4	Skilled	4	8,010 – 12, 019	4
Middle school	3	Semi-skilled	3	4,810 – 8, 009	3
Primary	2	Unskilled	2	1,601 – 4, 809	2
Illiterate	1	Unemployed	1	< 1,600	1

Age at onset of disease -

Duration of the disease -

Child attained puberty or not -

Frequency of blood glucose monitoring -

Carb-counting done or not -

Frequency of diabetic clinic visits –

ANTHROPOMETRY :

Height:

Weight:

BMI

INVESTIGATIONS:

HbA1c:

Form filled by Name-

Designation -

PATIENT INFORMATION SHEET

Place of study: Institute Of Child Health And Hospital for Children, Egmore, Chennai-8.

Name of Investigator: Dr. Asmita Chandramohan

Name of Participant: **Age**: **Sex**:

Hospital No:

Study title: GLYCEMIC CONTROL IN CHILDREN WITH TYPE 1 DIABETES MELLITUS -PREDICTORS AND IMPLICATIONS

We request your child to participate in the study.

Aim of the study-

This study aims at studying the predictors of poor glycemic control and its implications in the normal growth and development of the child with type 1 DM.

Methods-

In order to find out the answers to the above questions, we will be asking you questions about your child's details including demographic data, number of children at home, your education, profession, income and disease history. This will take approximately ten minutes.

Can I refuse to participate in the study?

Participation in the study is purely voluntary. You may refuse to participate or withdraw from the study at any time. In both cases the treatment and care your child receives from this hospital will not be affected in any manner.

Benefits of participating in this study:

Your child will not benefit directly by participating in this study. But by way of participating in this study, your child is contributing to information which when compiled, will yield useful information and will help in improving the quality of life in a diabetic child in the diabetic capital of the world.

Confidentiality-

The data collected from the study will be used for the purpose of study only. The results of the study will be published. Personal information of the children and parents participating in the study will be kept confidential. There will not be any disclosure about your child's information without your permission.

Subject rights-

If you wish further information regarding your child's rights as a research participant, you may contact the principal investigator in the mobile number or address mentioned below.

Principal Investigator – Dr. Asmita Chandramohan

Mobile number - 9840304789

Contact Address - MD Post graduate, Institute of Child Health and Hospital for Children, Halls road, Egmore, Chennai.

INFORMED CONSENT FORM

Study place: Institute Of Child Health And Hospital For Children,
Egmore, Chennai-8.

Title of the study GLYCEMIC CONTROL IN CHILDREN WITH TYPE 1 DIABETES MELLITUS -PREDICTORS AND IMPLICATIONS

Name of the investigator: Dr.ASMITA CHANDRAMOHAN

Name of the Participant: **Age**: **Sex**:

Hospital number:

1. I have read and understood the patient information sheet provided to me regarding the participation of my child in the study.

2. I have been explained about the nature of the study and had my questions answered to my satisfaction.

3. I have been explained about my rights and responsibilities by the investigator.

4. I will allow my child to cooperate with the investigator and undergo clinical tests subjected during the study whole heartedly.

5. I have been advised about the risks associated with my child's participation in this study.*

6. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my child's future treatment in this hospital. *

7. I hereby give permission to the investigators to release the information obtained from my child as result of participation in this study to medical journals/conference proceedings.

8. I understand that my child's identity will be kept confidential if my child's data are publicly presented/published.

. 9. I have decided my child can participate in the research study. I am aware that if I have any question during this study, I should contact the investigator.

10. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

Name and signature / thumb impression of the parent/guardian

Name _____ Signature_____

Date_____

Name and Signature of the investigator

Name _____ Signature_____

Date_____

Name and Signature of impartial witness 1:

Name _____ Signature_____

Date_____

Name and Signature of impartial witness 2:

Name _____ Signature_____

Date_____

CARB COUNTING HANDOUTS GIVEN TO THE PRIMARY CAREGIVER

உமது மருத்துவர் உங் உணவுக்கு எத்தனை பரிமாற்றங்கள் தேவைப்படும் என்று எடுத்துரைப்பார்கள்.

உதாரணத்திற்கு, 30 கிலோ குழந்தைக்கு 15 பரிமாற்றங்கள் தேவைப்படும் அளவு

காலை உணவு - 4

மதிய உணவு - 4

இரவு உணவு - 4

+ ஒரு சிற்றுண்டி (3) - 1×3 / 15

உங்கள் குழந்தைக்கு காலை உணவிற்கோ / இரவு உணவிற்கோ

i) இட்லி (3) + சாம்பார் (200 மி.லி) + தக்காளி சட்னி 4 / 100 மி.லி. = பரிமாற்றங்கள்

ii) பொங்கல் (240 கிராம்) + சாம்பார் (200 மி.லி.) = 4 பரிமாற்றங்கள்

மதிய உணவிற்கு:

i) சாதம் (240 கிராம்) - 1 கப் + 1 கப் சாம்பார் = 4 பரிமாற்றங்கள்

i) 2 சப்பாத்தி + 1/3 கப் சாதம் + பருப்பு (100 மி.லி) = 4 பரிமாற்றங்கள்

i) 3 சப்பாத்தி + 3/4 கொண்டைக்கடலை குழம்பு = 4 பரிமாற்றங்கள்

4 பரிமாற்றங்கள் மேல் எடுத்தால் (அதே இன்சுலின் அளவிற்கு) சர்க்கரை அளவு வெகு கூடுதல் ஆகலாம்

4 பரிமாற்றங்கள் கீழ் எடுத்தால், சர்க்கரை அளவு மிக குறைவு ஆகவும் வாய்ப்பு உண்டு

		கப்/ எண்ணிக்கை	கிராம்/மி.லி.	
1)	ரொட்டி	1	30	1
2)	இட்லி	1	55	1
3)	தோசை	1	50	1
4)	உப்மா/பொங்கல்/ கிச்சடி	1/3	80	1
5)	இடியாப்பம்	1	30	1
6)	அப்பம்	1	45	1
7)	பூரி	1	30	1
8)	சப்பாத்தி	1	30	1
9)	பரோட்டா	1	35	1
10)	பால்	1 1/4	300 மி.லி.	1
11)	தயிர்	1	250 மி.லி.	1
12)	அப்பிள்	1	100	1
13)	வாழை	1	60 g	1
14)	சீதாப்பழம்	1	65	1
15)	போர்த்தம்பழம்	2-3	20	1

16)	கொய்யாப்பழம்	1	135	1
17)	மாம்பழம்	1/3 கப்	90	1
18)	தர்பூசணி	1	220	1
19)	ஆரஞ்சு	1	130	1
20)	பப்பாளி	1/2 கப்	160	1
21)	அன்னாசிப்பழம்	3/4 கப்	120	1
22)	மாதுளை	1	100	1
23)	ஸ்ட்ரீம்	1/2 கப்	65	1
24)	ஜாம்	1 tbsp	20	1
25)	தேன்	1 tbsp	20	1
26)	சர்க்கரை	1 tbsp	20	1
27)	முருங்கை	1	25	1
28)	பக்கோடா	1/3 கப்	35	1
29)	மிக்சர்	1/3 கப்	40	1

சர்க்கரை இல்லாத உணவு வகைகள் :

1. தண்ணீர்
2. எள்ளெண்ணெய்
3. வெண்ணெய்
4. பாலாடைக்கட்டி (சீஸ்)
5. சூப்/சாலட்ஸ்
6. பன்னீர்

7. மீன் வகைகள்
8. கோழி
9. முட்டை
10. மட்டன்
11. நண்டு
12. இறால்

—X—

தகவல் படிவம்

ஆய்வு எண்

பெயர்

தலைப்பு : **வகை 1 நீரிழிவு நோயால் பாதிக்கப்பட்ட குழந்தைகளில் - முன்கூற்றுகளும், தாக்கங்களும்.**

தங்கள் குழந்தையும் இந்த ஆய்வில் பங்குபெற கேட்டுக் கொள்கின்றோம்.

1. வகை 1 நீரிழிவு நோய் குழந்தைகள் மத்தியில் பொதுவான நோயாகும்.

2. இந்நோயால் பாதிக்கப்பட்ட குழந்தைகளுக்கு வரும் சிக்கல்களும் இணை சீர்கேடுகளை கண்டறிவதே இந்த ஆய்வின் நோக்கமாகும்.

3. உங்கள் குழந்தையைப் பற்றிய தனிப்பட்ட விபரங்கள் யாருக்கும் தெரிவிக்காமல் பாதுகாக்கப்படும்.

4. இந்த ஆய்வில் பங்கு பெறுவது உங்கள் தனிப்பட்ட விருப்பமே. ஆய்வு ஆரம்பித்தபின் விருப்பமில்லையென்றால் தாங்கள் இந்த ஆய்வில் இருந்து விலகிக் கொள்ளலாம். அவ்வாறு விலகுவதானது தங்கள் குழந்தையின் சிகிச்சைக்கு எவ்வித பாதிப்பையும் உருவாக்காது.

5. ஆய்வின் முடிவுகள், ஆய்வு நடக்கும்போதே அல்லது ஆய்வு முடிந்த பின்னரோ தங்களுக்கு தெரிவிக்கப்படும். இந்த நீரிழிவு நோயால் பாதிக்கப்பட்டுள்ள மற்றும் வருங்காலத்தில் பாதிப்படையவுள்ள குழந்தைகளை முன் கூட்டியே கண்டறியவும், ஆரம்ப காலத்திலேயே மருத்துவ உதவி செய்யவும் பயன்படும்.

ஆய்வாளரின் கையொப்பம் ஆய்வில் பங்கேற்பவரின் பெற்றோரின் கையொப்பம்

ஆய்வாளரின் கையொப்பம் ஆய்வில் பங்கேற்பவரின் பெற்றோரின் கையொப்பம்

இடம் :

தேதி :

ஒப்புதல் படிவம்

ஆய்வு எண்
பெயர் :
தேதி :

ஆய்வின் தலைப்பு : வகை 1 நீரிழிவு நோயால் பாதிக்கப்பட்ட குழந்தைகளில் - முன்கூற்றுகளும், தாக்கங்களும்.

நான் திருமதி..... அரசு குழந்தைகள் நல மருத்துவமனை மற்றும் ஆராய்ச்சி நிலையத்தில் சேர்ந்துள்ளேன். மருத்துவமனை எண்..... இடம் எழும்பூர்.

குழந்தைகளில் நீரிழிவு நோயின் முன்கூற்றுகளும், தாக்கங்களும் ஆய்வைப் பற்றி - மருத்துவர் என்னிடம் தெளிவாக கூறினார்.

நான் இந்த ஆய்விற்கான ஒப்புதலை, இந்த ஆய்வு பற்றி முழுவதும் அறிந்தபின்பே அளித்தேன். இந்த ஆய்வில் எவருடைய வேண்டுகோளும் இல்லாமல் பங்கேற்கிறேன். நான் இந்த ஆய்வில் இருந்து எந்நேரத்திலும் விலகிக் கொள்ளலாம் என்பதையும் அதற்காக சிகிச்சை எந்தவிதத்திலும் தடைப்படாது என்பதையும் மருத்துவர் மூலம் அறிந்து கொண்டேன். நான் மருத்துவரின் கேள்விகளுக்கு பதிலளிக்க முழு மனதுடன் ஒப்புதல் அளிக்கிறேன்.

ஆய்வாளரின் கையொப்பம் ஆய்வில் பங்கேற்பவரின் கையொப்பம்

இடம் :

தேதி :

serial number	name	age	height	weight	bmi	sex	residence	birth order	family history	mother's age	education	employment code	father's age	education	employment code	family income	primary caretaker	living with parents	age at onset	duration of disease	puberty attained	frequency of smbg	carb counting	frequency of clinic visits	height	weight	bmi	HbA1c before carb counting	after carb counting
1	hauwini	12.5	143	32	15.6	1	1	2	aternal au	38	6	4	39	3	1	10,000	mother	yes	5y7m	7y	no	once weekl	yes	nce a mon	143	32	15.6	7.2	5.6
2	sharika	9	124	24	15.6	1	2	1	-	29	4	1	35	4	2	$000	mother	yes	8	1y	no	once weekl	yes	nce a mon	124	24	15.6	8.8	9.1
3	lydia	15	156	60	24.6	1	1	1	mother	42	5	4	44	4	3	10,000	mother	yes	6	9y	yes	daily	yes	very 20 da	156	60	24.6	10.2	9.8
4	Sruthi	14	150	42	18.6	1	1	1	-	34	6	1	44	5	2	$000	mother	yes	1	13y	yes	once a wee	yes	nce a mon	150	42	18.6	7.2	6.8
5	Akash	13	154	43	18.13	2	1	1	-	32	3	2	34	3	2	8,000	mother	yes	12	1y	no	once a wee	yes	ce in 2 wee	154	43	18.13	7.8	7.5
6	Bharath	13	138	30	15.7	1	2	1	randfathe	37	3	2	47	4	2	$000	mother	yes	3	10y	no	once a wee	no	nce a mod	138	30	15.7	11.5	10.2
7	anusha	15	140	43	21.9	1	1	1	-	38	2	2	44	3	3	10,000	mother	yes	11	4y	yes	once a wee	yes	very 15 da	140	43	21.9	10	9.8
8	jai deepika	9	140	29	14.7	1	2	2	-	27	3	2	34	3	4	6000	mother	yes	7	2y	no	once a wee	yes	in three m	140	29	14.7	9	7.8
9	sachika	14	132	25	14.36	1	1	2	-	36	2	1	49	3	3	6,000	mother	yes	8	6y	no	once a wee	yes	nce a mon	132	25	14.36	14.2	13.5
10	yovel	12	142	29	14.42	2	2	2	-	33	4	1	37	3	2	6000	mother	yes	10	2y	no	once a wee	yes	monthly	142	29	14.42	10.2	9.2
11	naveenkumar	8.5	116	20	14.8	2	2	1	-	26	4	1	36	3	2	10,000	mother	yes	1.5y	7y	no	once a wee	yes	monthly	116	20	14.8	9.8	9
12	sasthanalakshu	10.5	145	35	16.67	1	2	2	-	43	3	3	48	3	3	10,000	mother	yes	6	4y	no	once a wee	yes	monthly	145	35	16.67	6.2	5.8
13	karthik	12.5	151	36	16	2	2	3	-	50	1	2	62	1	2	6,000	mother	no	4.5y	8y	yes	once a wee	yes	rice a mon	151	36	16	8	6.6
14	naveenkumar	13	137	26	13.9	2	2	2	-	34	2	3	41	2	3	6,000	mother	yes	5y	8y6m	no	once a wee	yes	mothly	137	26	13.9	7	7.7
15	nivas pandi	7	117	20	17.09	2	1	2	-	33	4	3	40	5	3	11,000	mother	yes	2.5y	4.5y	no	once a wee	yes	monthly	117	20	17.09	8	6.6
16	swapna	9	125	23	14.7	1	1	1	-	40	5	4	45	5	5	10,000	mother	yes	3y	5y6m	no	once a wee	yes	monthly	125	23	14.7	10	11.2
17	harish kumar	15	152	37	16	1	2	1	-	33	2	1	38	2	3	7,000	mother	yes	12y	2.5y	yes	once a wee	yes	monthly	152	37	16	11	9.9
18	jananipriya	7	112	18	14.3	1	2	2	-	30	2	2	38	2	3	10,000	mother	yes	40days	7y	no	once a wee	yes	monthly	112	18	14.3	10.2	10.6
19	thamizharasi	7	108	19	16.3	1	1	2	-	31	6	6	41	5	4	8,000	mother	yes	4	3y	no	once a wee	yes	monthly	108	19	16.3	8.8	6.7
20	kaviyarasu	9	108	20	18	2	2	2	-	29	3	2	34	1	2	5,000	mother	yes	7y	2y	no	once a wee	yes	e in 2 mo	108	20	18	6.6	8
21	hariharan	10	132	25	14.36	2	1	1	-	32	4	1	40	4	3	15,000	mother	yes	5	5y	no	once a wee	yes	monthly	132	25	14.36	12	10.8
22	hariharan	11	130	27	15.9	2	2	1	randmothe	31	4	1	39	4	3	6,000	father	yes	9	2y	no	once a wee	yes	monthly	130	27	15.9	11	8.9
23	rajkiran	9	129	25	15.03	2	2	2	randparen	30	4	1	35	5	4	10,000	mother	yes	5	3.5y	no	once a wee	yes	monthly	129	25	15.03	12.2	10
24	gayathri	12	144	36	17.3	1	2	2	-	42	4	1	47	4	4	12,000	mother	yes	10	1.5y	no	once a wee	yes	monthly	144	36	17.3	11.2	10.2
25	kamali	15	158	45	18	1	1	1	-	43	4	3	48	3	3	16,000	mother	yes	9	6y	yes	once a wee	yes	r months	158	45	18	8	7.5
26	varalakshmi	13	149	44	19.8	1	1	1	-	36	3	1	44	3	3	10,000	mother	yes	9	4.5y	yes	once a wee	yes	monthly	149	44	19.8	14.4	13
27	dhanush	14	143	42	20.5	2	2	1	-	39	3	1	41	3	4	8,000	mother	yes	8	5.5y	yes	once a wee	yes	monthly	143	42	20.5	10	10.2
28	sharika	7	119	22.5	15.5	1	1	2	mother	34	4	3	38	4	3	8,000	mother	yes	5	2y	no	once a wee	yes	monthly	119	22.5	15.5	12	10.5
29	hamundeeswa	12	155	39	16.2	1	2	1	er, grandfa	32	4	1	36	5	3	9,500	mother	yes	11y	2y	yes	once a wee	yes	monthly	155	39	16.2	12.8	13.9
30	pavithra	13	150	35	15.6	1	1	2	-	38	3	1	42	3	4	12,000	mother	yes	1.5y	11.5y	yes	once a wee	no	in three m	150	35	15.6	12	12.5
31	swathi	15	156	55	22.9	1	1	2	randfathe	33	2	3	40	1	3	5,000	mother	yes	11y	4y	yes	once a wee	yes	in two mo	156	55	22.9	11	11.3
32	kumaravel	13	144	32	14.9	2	2	3	dfather,si	35	3	1	40	4	3	4,000	mother	yes	4y	9y	no	once a wee	yes	e months	144	32	14.9	7	6.1
33	kowsalya	15	160	47	18.4	1	2	2	ffather, br	35	3	1	40	4	3	4,000	mother	yes	8	7y	no	once a wee	yes	e months	160	47	18.4	7.8	8.2
34	sanjana	7	118	20	14.4	1	1	2	randparen	33	3	1	38	1	2	5,000	mother	yes	4y	3y	no	once a wee	no	eemonths	118	20	14.4	5.9	6.1
35	chandru	10	127	22	13.6	2	1	2	randfathe	29	4	3	36	4	3	20,000	mother	yes	6y	4y	no	once a wee	yes	months o	127	22	13.6	9	9.8
36	selvi	9	130	22.5	13.3	1	2	2	cousin	27	1	2	35	4	2	10,000	mother	yes	5y	4y	no	once a wee	no	e months	130	22.5	13.3	12	13.3
37	rithanya	13	137	27	14.4	1	1	1	randmothe	31	5	4	32	4	3	22,000	mother	yes	7y	6y	no	once a wee	yes	months o	137	27	14.4	10.3	8.4
38	harini	15	141	40	20.1	1	1	1	-	32	3	1	37	3	3	10,000	mother	yes	4y	11y	yes	weekly	yes	monthly	141	40	20.1	8.9	8.1
39	thamizharasan	8	125	24	15.4	2	2	3		38	1	2	41	2	2	7,000	mother	yes	4y	4y	no	once a wee	yes	monthly	125	24	15.4	8.1	9.1
40	bhavadharani	14	150	33	14.7	1	2	2	-	32	4	1	36	3	2	8,000	mother	yes	10y	4y	no	once a wee	yes	irregular	150	33	14.7	10.1	14.1
41	vignesh	15	162	39	14.9	2	1	3	-	45	3	1	56	3	2	7,500	mother	yes	2y	13y	no	once a wee	yes	monthly	162	39	14.9	10.3	9.8
42	nalina	12	143	40	19.6	1	2	2	aunt	36	2	2	42	3	2	8,500	mother	yes	11y	1y	no	once a wee	yes	monthly	143	40	19.6	7	7
43	adma vaishnav	11	149	39.5	17.8	1	2	1	father	40	4	1	42	5	4	10,000	mother	yes	10 y	1y	no	once a wee	yes	e months	149	39.5	17.8	13.8	12.6
44	sathish kumar	11	134	27	15	2	1	1	-	30	2	1	40	2	2	5,000	mother	yes	9y	2y	no	once a wee	yes	months o	134	27	15	9.2	8.6
45	priya	13	143	35	17.1	1	1	1	-	32	3	2	40	3	2	8,500	mother	yes	8y	5y	yes	once a wee	yes	monthly	143	35	17.1	9.2	8.5
46	anusha	7	113	19	14.9	1	2	1	randparen	32	3	1	45	3	2	10,000	mother	yes	3y	4y	no	once a wee	yes	monthly	113	19	14.9	11.2	9.6
47	hariharan	15	160	48	18.7	2	2	1	father	37	3	1	45	3	2	7,000	mother	yes	8y	7y	no	once a mon	yes	in two mo	160	48	18.7	12.8	11.5
48	john joseph	13	155	39	16.2	2	2	2	-	47	2	1	49	4	4	10,000	mother	yes	12y	1y	no	once a wee	yes	monthly	155	39	16.2	6.6	7
49	anish fathima	14	153	34	14.5	1	1	1	-	31	4	1	31	3	2	15,000	mother	yes	7y	7y	yes	once a wee	yes	monthly	153	34	14.5	9.5	9
50	harini	6	105	15	13.6	1	1	1	-	25	4	1	29	3	2	10,000	mother	yes	5y	1y	no	once a wee	yes	in two mo	105	15	13.6	10.2	10.1
51	raja	15	159	41	16.2	2	2	2	-	38	3	1	42	2	1	5,000	mother	yes	11y	4y	no	once a mon	yes	in three m	159	41	16.2	9.2	9.4
52	sathish	12	140	30	15.3	2	2	2	-	34	3	1	37	3	2	10,000	mother	yes	9y	3y	no	once a wee	yes	e months	140	30	15.3	8.2	7.6
53	rahul	12	138	31	16.3	2	1	3	-	45	3	1	48	3	2	6,500	mother	yes	11y	1y	no	once a wee	yes	monthly	138	31	16.3	8.7	12.5

54	sharmila	14	141	27	13.6	1	1	1	-	36	4	1	43	2	3	20,000	mother	yes	12y	1y	no	rice a mon	yes	monthly	141	27	13.6	8	7.3
55	chithirai selvan	8	121	20	13.8	2	1	1	-	30	2	1	42	1	2	9,000	mother	yes	6y	2y	no	urice a wee	yes	rice a mon	121	20	13.8	9	9
56	mohanapriya	13	141	29	14.5	1	1	1	-	39	6	5	40	4	3	15,000	mother	yes	10y	3y	no	nce a wee	yes	monthly	141	29	14.5	10.2	9.6
57	nafisha	12	133	23	13	1	2	2	randmothe	40	1	1	43	1	3	10,000	mother	yes	2y	8y	no	rice a wee	yes	monthly	133	23	13	14.5	12.8
58	harwini	13	143	32	15.6	1	1	2	aunt	38	6	4	39	3	1	10,000	mother	yes	6y	7y	no	rice a wee	yes	monthly	143	32	15.6	11.2	10.6
59	jayasurya	11	137	24	12.8	2	1	3	-	33	2	3	40	2	2	5,000	grandpares	no	1y	10y	no	rice a wee	yes	monthly	137	24	12.8	9.6	10.3
60	surya	10	125	22	14.1	2	1	1	-	30	3	1	42	3	3	10,000	mother	yes	1y	9y	no	rice a wee	yes	rice a mon	125	22	14.1	9.3	9.4
61	abinaya	10	139	30	15.5	1	2	1	-	31	4	1	38	5	4	35,000	mother	yes	4y	6y	no	rice a wee	yes	rice a mon	139	30	15.5	8.5	8
62	divyabharathi	13	143	36	17.6	1	2	2	grandfathe	43	3	5	48	3	3	18,000	mother	yes	7y	6y	no	rice a wel	yes	in two mo	143	36	17.6	14.4	13.5
63	vignesh	12	135	30	16.5	2	2	2	-	37	3	1	39	1	2	7,500	mother	yes	11y	1y	no	rice a wee	yes	in two mo	135	30	16.5	9.8	10.4
64	siju	11	142	65	32.2	2	1	2	-	35	3	1	44	3	2	6,000	mother	yes	1y	10y	no	rice a wee	yes	monthly	142	65	32.2	10.2	9.5
65	nivedha	12	143	36	17.6	1	2	2	-	40	5	1	47	5	3	15,000	mother	yes	11y	1y	no	rice a wee	yes	months o	143	36	17.6	8	7.7
66	meenakshi	7	123	23	15.2	1	1	2	-	33	3	1	37	1	2	8,000	mother	yes	6y	1y	no	rice a wee	yes	in two mo	123	23	15.2	12.8	10.8
67	gopika	9	116	22	16.3	1	1	2	-	32	3	1	37	3	2	10,000	mother	yes	8y	1y	no	rice a wee	yes	months o	116	22	16.3	8.8	7.8
68	madhibala	12	128	28	17.1	2	1	1	-	30	3	1	34	4	2	8,500	mother	yes	2y	10y	no	irregular	yes	monthly	128	28	17.1	12.4	10.8
69	sneka	13	144	37	17.8	1	2	2	-	32	3	1	38	3	2	7,500	mother	yes	11y	2y	no	rice a wee	yes	e months	144	37	17.8	12	11.2
70	rohith	7	109	18	15.2	2	1	1	-	26	3	1	30	1	2	6,000	mother	yes	6y	1y	no	rice a wee	yes	monthly	109	18	15.2	6.2	5.8
71	atriya	12	150	38	16.9	1	1	1	father	31	3	1	40	5	3	10,000	mother	yes	10y	2y	no	rice a wee	yes	in two mo	150	38	16.9	11.8	10.7
72	Prashanth	8	121	20	13.7	2	1	1	-	30	1	2	40	1	2	8,000	mother	yes	5y	3y	no	rice a wee	yes	monthly	121	20	13.7	9.8	9
73	subash	14	147	35	16.2	2	1	1	-	35	3	2	39	2	2	6,000	mother	yes	4y	10y	no	rice a wee	yes	in two mo	147	35	16.2	14.4	12.9
74	rimsharuman	13	151	46	20.2	1	2	2	randmothe	35	3	1	37	3	2	10,000	mother	yes	11y	2y	yes	rice a wee	yes	e in 2 mon	151	46	20.2	9.4	8.8
75	rohith kumar	12	141	34	17.1	2	1	1	randmothe	30	4	1	38	3	2	10,000	mother	yes	4y	8y	no	rice a wee	yes	e in 2 mon	141	34	17.1	10.8	9.8
76	harish	10	120	24	16.7	2	2	1	-	35	2	1	39	3	1	10,000	mother	yes	8y	2y	no	urice a wee	yes	monthly	120	24	16.7	6	5.8
77	nitheeshwaran	5	118	24	17.2	2	1	2	father	33	3	1	39	5	4	15,000	mother	yes	2y	3y	no	urice a wee	yes	e months	118	24	17.2	10.8	9.5
78	amritha	14	153	45	19.2	1	1	1	father	42	3	1	46	3	2	10,000	mother	yes	12y	2y	yes	rice a wee	yes	e months	153	45	19.2	7.2	7
79	durga	14	152	55	23.8	1	2	1	-	42	3	1	45	3	2	10,000	mother	yes	9y	5y	yes	rice a wee	yes	e months	152	55	23.8	14	12.3
80	bhavadharani	14	151	43	18.9	1	2	2	-	38	4	1	48	7	7	40,000	mother	yes	11y	3y	yes	rice a wee	yes	e months	151	43	18.9	8.9	10.1
81	sivapriya	8	125	23	14.7	1	1	1	-	40	5	4	45	5	5	10,000	mother	yes	3y	5y	no	rice a wee	yes	monthly	125	23	14.7	11.2	9.3
82	swetha	7	125	21	13.4	1	2	2	-	35	3	1	39	4	3	15,000	mother	yes	3y	4y	no	rice a wew	yes	monthly	125	21	13.4	8.2	7.79
83	harikrishnan	10	128	28	17.1	2	1	1	-	38	3	1	46	3	2	8,500	mother	yes	3y	7y	no	rice a wee	yes	monthly	128	28	17.1	11.2	10
84	vidhya	8	116	22	16.3	1	1	1	-	32	3	2	40	4	3	12,000	mother	yes	5y	3y	no	wice a wee	yes	monthly	116	22	16.3	10.8	9.9
85	sujithra	9	130	27	16	1	2	2	-	35	3	1	42	4	2	10,000	mother	yes	4y	5y	no	rice a wee	yes	monthly	130	27	16	8.9	8.7
86	lavanya	7	122	20	13.2	1	1	1	-	30	4	2	34	3	2	10,000	mother	yes	5y	2y	no	rice a wee	yes	monthly	122	20	13.2	14.8	14.7
87	soundarya	14	156	42	17.3	1	2	1	-	38	3	1	42	4	2	15,000	mother	yes	4y	10y	yes	rice a wee	yes	months o	156	42	17.3	7.8	7.6
88	ishwarya	7	127	24	14.9	1	1	1	-	34	3	1	38	4	2	10,000	mother	yes	3y	4y	no	rice a wee	yes	monthly	127	24	14.9	9.5	9
89	shamshad	8	132	29	16.1	2	2	2	-	38	3	2	44	2	2	7,500	mother	yes	4y	4y	no	rice a wee	yes	monthly	132	29	16.1	12.8	11
90	abinayashree	10	130	28	16.6	1	1	2	-	36	4	3	44	4	4	12,000	mother	yes	6y	4y	no	rice a wee	yes	monthly	130	28	16.6	14.8	12.6
91	jennifer	7	124	24	15.6	1	1	1	-	28	4	1	32	4	3	10,000	mother	yes	3y	4y	no	rice a wee	yes	monthly	124	24	15.6	11	11.3
92	prakash	12	138	30	15.8	2	1	1	-	34	3	1	40	3	2	7,500	mother	yes	6y	6y	no	rice a wee	yes	monthly	138	30	15.8	11.3	11
93	pavan kumar	7	124	28	18.2	2	2	1	-	29	3	1	35	3	2	10,000	mother	yes	5y	2y	no	rice a wee	yes	monthly	124	28	18.2	12.8	14.3
94	keerthana	10	128	24	14.6	1	2	3	-	34	4	2	36	4	2	15,000	mother	yes	6y	4y	no	rice a week		monthly	128	24	14.6	9.4	9.6
95	sivagami	14	140	36	18.4	1	1	1	-	40	3	1	44	4	3	12,000	mother	yes	8y	6y	yes	rice a wee	yes	months o	140	36	18.4	9.5	8.4
96	thulasi	12	134	38	21.2	1	2	1	-	37	3	1	41	3	2	7,000	mother	yes	5y	7y	no	rice a wee	yes	monthly	134	38	21.2	11	10.1
97	imran	8	124	28	18.2	2	1	2	-	29	4	1	36	4	2	12,000	mother	yes	4y	4y	no	rice a wee	yes	months o	124	28	18.2	13.2	12
98	shree	6	115	22	16.6	1	2	1	-	28	4	2	33	4	3	15,000	mother	yes	5y	1y	no	rice a wee	yes	monthly	115	22	16.6	10	8.8
99	solomon	9	130	28	16.6	2	2	2	-	32	4	1	37	3	2	8,000	mother	yes	5y	4y	no	rice a wee	yes	monthly	130	28	16.6	13.5	12.1
100	murugan	7	122	22	14.8	2	1	1	-	29	4	2	32	3	2	10,000	mother	yes	6y	1y	no	rice a wee	yes	monthly	122	22	14.8	10.2	9.6
101	manoj kumar	9	121	23	15.7	2	1	1	-	34	3	1	37	4	2	10,000	mother	yes	6y	3y	no	rice a wee	yes	monthly	121	23	15.7	9.5	6.8
102	santhoshi	6	114	20	15.4	1	1	1	-	32	3	1	35	4	2	10,000	mother	yes	4y	2y	no	rice a wee	yes	monthly	114	20	15.4	8.2	10
103	rajkiran	9	115	16	12.1	2	2	1	-	36	2	1	42	3	2	7,500	mother	yes	5y	4y	no	rice a wee	yes	e months	115	16	12.1	10.2	9.7
104	amritha	13	153	45	19.2	1	2	2	-	40	3	1	44	4	2	10,000	mother	yes	11y	2y	no	rice a wee	yes	e months	153	45	19.2	6.4	7
105	sowmya	13	149	40	18	1	1	1	-	38	4	2	42	4	2	15,000	mother	yes	6y	7y	no	nce a wee	yes	months o	149	40	18	7.7	8.8
106	balaji	5	128	27	16.5	2	2	2	-	33	3	1	36	3	2	7,500	mother	yes	2y	3y	no	rice a wee	yes	monthly	128	27	16.5	7.9	12.4
107	sadhana	8	124	24	15.6	1	1	1	-	32	4	2	36	4	2	12,000	mother	yes	4y	4y	no	rice a wee	yes	monthly	124	24	15.6	8.9	9.5
108	vishakh	8	122	26	17.5	2	2	1	-	35	4	1	39	4	2	10,000	mother	yes	2y	6y	no	rice a wee	yes	monthly	122	26	17.5	11.2	12
109	santhosh	9	130	29	17.2	2	2	2	-	39	3	1	42	4	2	8,000	mother	yes	4y	5y	no	nce a mon	yes	e months	130	29	17.2	10.6	9.3
110	jeeva	9	137	28	14.7	2	2	1	-	32	3	1	39	3	2	10,000	mother	yes	7y	2y	no	rice a wee	yes	monthly	137	28	14.7	10.7	9.3
111	karthik	5	98	15	15.6	2	3	2	-	39	2	1	48	3	2	7,000	mother	yes	4y	1y	no	rice a wee	yes	e months	98	15	15.6	12.6	11.8
112	trisha	11	137	42	22.4	1	1	1	-	33	3	1	36	4	2	10,000	mother	yes	8y	3y	no	rice a wee	yes	monthly	137	42	22.4	12.9	11.5